Dissertation on

ANALYSIS OF EFFICACY OF CORNEAL COLLAGEN CROSSLINKING PROCEDURE (C3-R) AS A THERAPEUTIC MODALITY IN KERATOCONUS

Submitted in partial fulfillment of requirement of

M.S. OPHTHALMOLOGY

BRANCH-III

REGIONAL INSTITUTE OF OPHTHALMOLOGY
and GOVT. OPHTHALMIC HOSPITAL
MADRAS MEDICAL COLLEGE
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CERTIFICATE

This is to certify that the dissertation entitled , **"ANALYSIS OF EFFICACY OF CORNEAL COLLAGEN CROSSLINKING PROCEDURE (C3-R) AS A THERAPEUTIC MODALITY IN KERATOCONUS"** submitted by **DR. R. SUJATHA**, in partial fulfillment for the award of the degree of Master of Surgery in Ophthalmology by **The Tamilnadu Dr. M.G.R. Medical University, Chennai** is a bonafide record of the work done by her in the Regional Institute of Ophthalmology and Government Ophthalmic Hospital, Egmore, Chennai, during the academic year 2010-2013.

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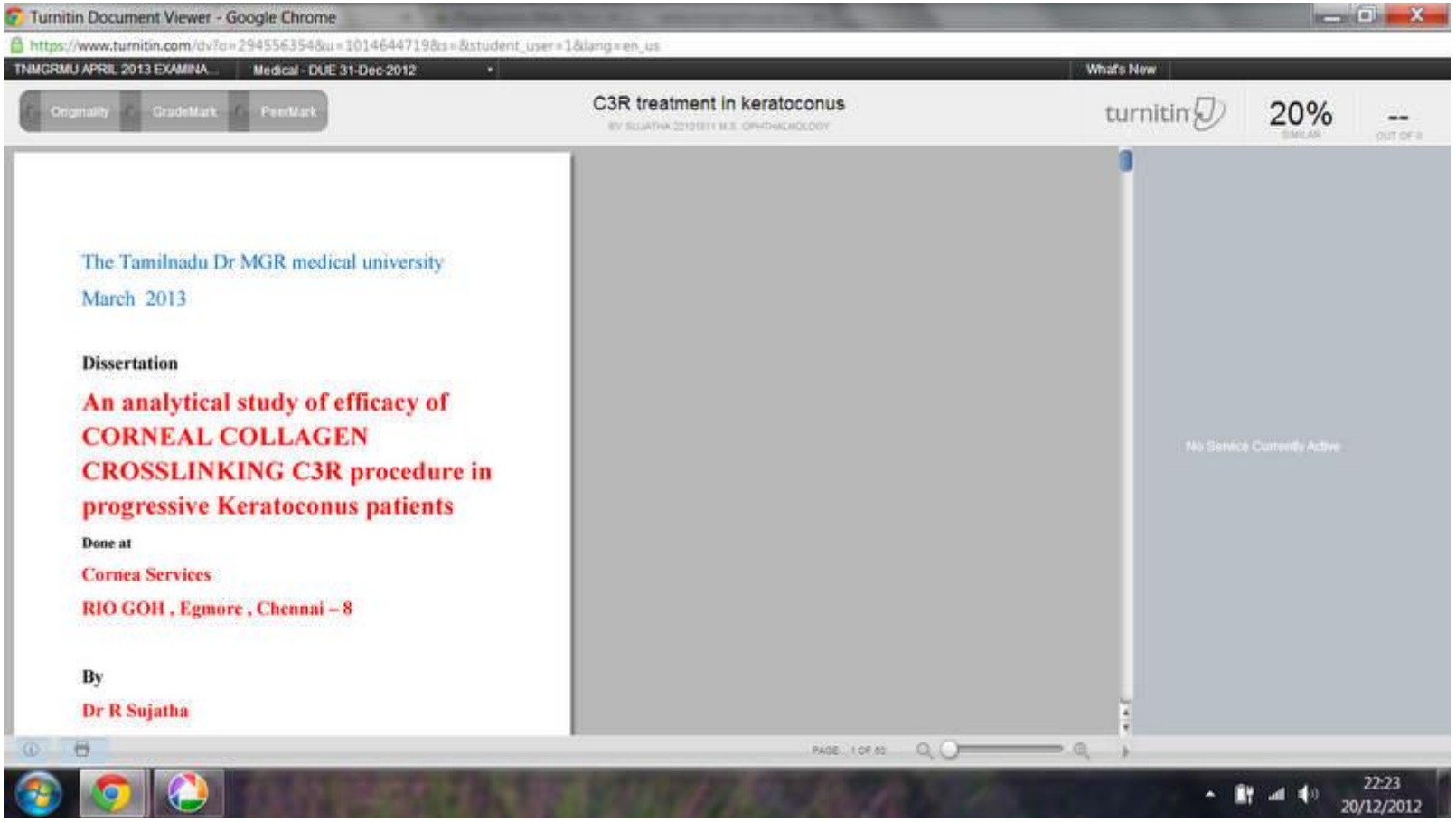
Finally, I am greatly indebted to all my patients for their cooperation which made this study possible. I dedicate this thesis work to the blessings of God almighty.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CERTIFICATE OF APPROVAL

To
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Dear Dr. R. Sujatha

The Institutional Ethics Committee of Madras Medical College reviewed and discussed your application for approval of the proposal entitled "Analysis of Efficacy of Corneal Collagen Cross – linking procedure (C3-R) as a therapeutic modality in Keratoconus " No.28092011

The following members of Ethics Committee were present in the meeting held on 27.09.2011 conducted at Madras Medical College, Chennai –3

1. Dr. S.K. Rajan MD	-- Chairperson
2. Dr. V. Kanagasabai MD Dean, Madras Medical College, Chennai -3	-- Deputy Chairman
3. Prof. R. Sundaram MD Vice Principal, Madras Medical College, Chennai -3	-- Member Secretary
4. Prof. R. Nandhini MD Director , Inst. of Pharmacology, MMC , Ch-3	-- Member
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6. Thiru . Ulaganathan Administrative Officer, M M C, Ch-3	-- Layperson
7. Thiru. S. Govindasamy BA BL	-- Lawyer
8. Tmt. Arnold Saulina .MA., MSW	-- Social Scientist

We approve the Proposal to be conducted in its presented from

Sd/ Chairman & Other Members

The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study , any changes in the protocol and patient information / informed consent and asks to be provided a copy of the final report.

Member Secretary, Ethics committee

CONTENTS

INTRODUCTION

Keratoconus is a bilateral non inflammatory degenerative condition that compromises the structural integrity of collagen matrix within the corneal stroma. The hallmark characteristic is the development of a localised cone shaped ectasia accompanied by thinning of the stroma in the area of cone.

A high degree of irregular, myopic astigmatism results, causing a variable amount of visual impairment. The prevalence of keratoconus is approximately 54.5 per 100,000 population. The average annual incidence rate is 2 per 100,000 population.

Corneal Collagen Crosslinking procedure is a new approach to increase the mechanical and chemical stability of corneal tissue. This procedure was first developed by Prof. Theo Seiler, Prof .Wollensak and Prof.Eberhard Spoerl in 1998 at the University of Dresdan, Germany. The primary aim of the treatment is to create additional bonds inside the stroma by means of highly localised polymerization while minimizing exposure to the surrounding structure of the eye.

HISTORY

In 1748, German oculist Burchard Mauchart provided an early description of a case of keratoconus, which he called Staphyloma diaphanum.

In 1854, British physician John Nottingham clearly described Keratoconus and distinguished it from other ectasia of the cornea.

In 1859, British surgeon William Bowman used an ophthalmoscope to diagnose Keratoconus. He also attempted to restore the vision by pulling on the iris with a fine hook inserted throughout the cornea and stretching the pupil into vertical shape.

In 1869, Swiss ophthalmologist Johann Horner wrote a thesis on the " Treatment of Keratoconus".

In 1882, Placido placed an observation hole in the centre of the target. His target was a disc bearing alternate black and white concentric rings and this pattern still forms the basis of many topographic systems.

In 1890, a Scottish Physicist, Sir James Alfred Ewing introduced the term Corneal Hysteresis.

In 1896, Gullstrand applied photography to keratoscopy (photokeratoscopy)

In 1936, Roman Castroviego performed first successful corneal transplantation.

In 1998, Corneal Collagen Crosslinking procedure was first developed by Prof. Theo Seiler, Prof. Wollensak and Prof. Eberhard Spoerl at the university of Dresdan, Germany.

ANATOMY

Cornea is a transparent avascular tissue which forms the principal refractive surface, accounting for 70% of total refractive power.It forms the anterior 1/6th of the eyeball.

DIMENSIONS

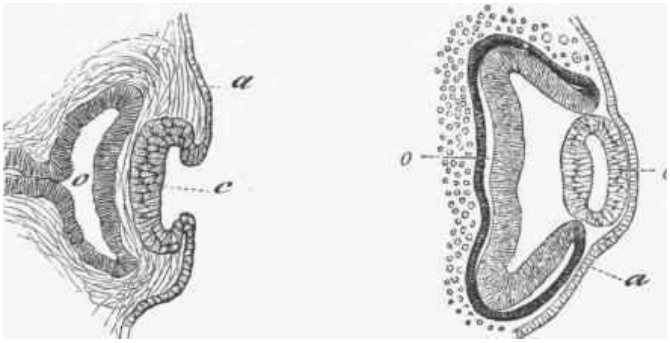
Cornea appears elliptical, being 11.7mm wide in the horizontal meridian and 10.6mm in the vertical. The posterior surface of the cornea is circular about 11.7mm in diameter.The thickness of the cornea is 0.52mm with a peripheral thickness of 0.67mm.The surface area is about 1.3cm2, one sixth of the surface area of the globe.

Cornea is more curved in the vertical than the horizontal meridian giving rise to 'with the rule astigmatism' .In the optical zone the radius of curvature of anterior surface is 7.8mm and posterior surface is 6.5mm

DEVELOPMENT OF THE EYE

The development of the cornea is always associated with that of the anterior chamber which begins to develop by the end of VIth week of intrauterine life (17-18mm stage). The area between the surface epithelium and the anterior surface of the lens is occupied by loosely

organised mesenchymal tissue, a narrow slit appears in the mesoderm which continues to enlarge , separating the mesoderm into an anterior layer which forms the corneal stroma and posterior layer which forms the stroma of the iris.

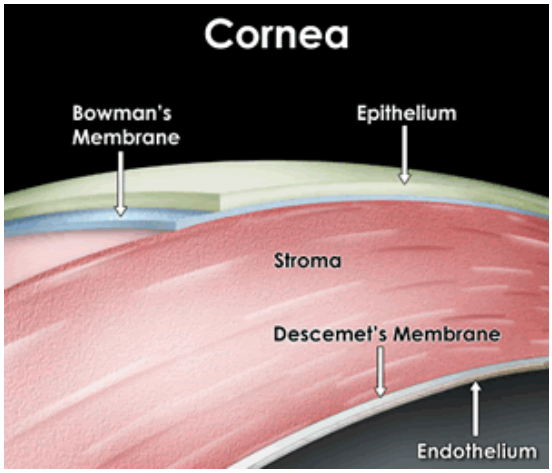


The corneal endothelium begins to form soon after the anterior chamber appears. Mesodermal cells grow in from the periphery to form the flattened endothelial cells. These cells later secrete the structureless hyaline membrane called descemets membrane. By the end of 30mm stage, all these changes are completed.

The surface ectoderm overlying these mesodermal stroma develop into corneal epithelium. Bowmans membrane is developed in most superficial layer of the stroma by fifth month.

Layers of cornea

1. Epithelium
2. Bowmans layer
3. Stroma
4. Descemets membrane
5. Endothelium



EPITHELIUM

The corneal epithelium is stratified, squamous and non keratinised. It is 50-90mum thick and consist of five to six layers of nucleated cells.

It has morphologically three layers

a) single layer of columnar basal cells

b) 2 to 3 layers of wing cells

c) 2 to 3 layers of superficial squamous cells

The deepest of these cells, the basal cells are single layered columnar cells and forms the germinative layer of the epithelium. The wing cells consist of polyhedral cells which send process between the basal cells. Each cell contain an oval nucleus, whose long axis is parallel with surface of cornea. The surface cells are 2 to 3 layer polyhedral cells which become wider and flattened towards surface.

Corneal epithelial cells are tightly adherent to each other and the underlying structures by means of specialized junctions. Other than epithelial cells, melanocytes, Langerhans cells and leucocytes are present within the epithelial layer. Langerhans cells are modified macrophages and play a role in ocular hypersensitivity and immunological phenomenon by processing antigens and presenting them to lymphocytes.

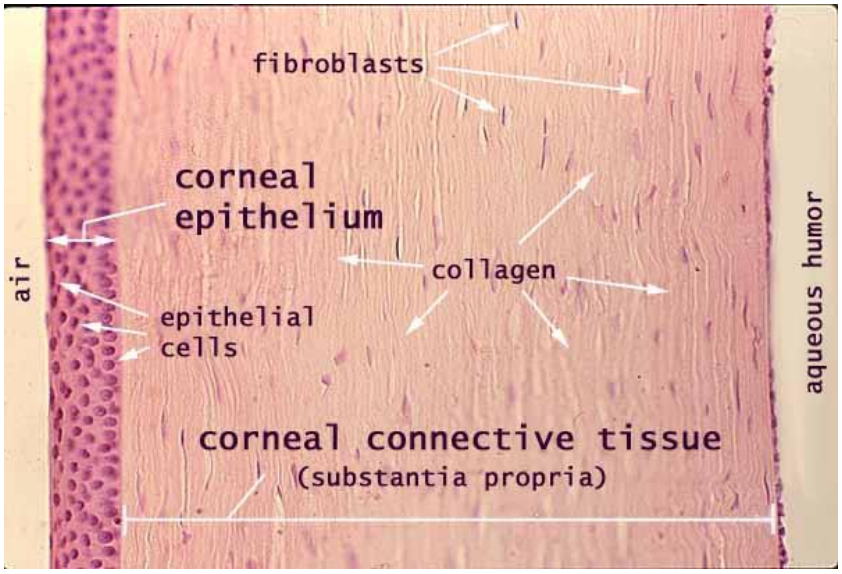
BASEMENT MEMBRANE

It presents as a uniform hyaline like appearance. Anteriorly, it closely follows the posterior surface of basal cells and posteriorly it rests on the bowmans membrane.

BOWMANS LAYER (anterior limiting lamina)

A narrow, acellular homogenous zone, 8-14 microns thick, subjacent to the basal lamina of the corneal epithelium. It is separated from the epithelium by sharply defined border. Posteriorly the line of demarcation from the stroma is ill defined. It is composed of a network of fine randomly oriented collagen fibrils. Once damaged it cannot be regenerated. It shows a good deal of resistance to injury or infection.

STROMA (substantia propria)



The stroma, about 500 microns thick , consist of regularly arranged lamellae of collagen fibres. They lie in a proteoglycan ground substance (chondroitin sulphate and keratan sulphate) interspersed with modified keratocytes. Maintenance of the regular arrangement and spacing of

collagen is crucial for optical clarity. The stroma cannot regenerate following damage. The repair of the stroma after injuries involve keratocyte activation, migration and fibroblast transformation and formation of scar tissue.

DESCEMETS MEMBRANE (posterior limiting layer)

Descemets membrane is the basal lamina of the corneal endothelium. It consist of an anterior banded zone and a posterior non banded zone and has regenerative potential. Its peripheral lamellation visible by gonioscopy is known as Schwalbe line. It is composed predominantly of type IV collagen and glycoprotein including fibronectin.

At the periphery of the cornea, the posterior surface of the membrane presents as rounded wart like elevation, the Hassal Henle bodies which tend to increase with age.

ENDOTHELIUM

The endothelium consist of a monolayer of polygonal cells. The cells maintain deturgescence by pumping excess fluid out of stroma. The adult cell density is 2500cells/sqmm. The number of cells decrease 0.6%

per year and cells cannot regenerate and when cell density is <500 cells corneal edema occurs .

COLLAGEN

The ocular collagen types include fibrous collagen I,II,III and V., non fibrous collagen type IV and filamentous collagen types VI,VIII,IX, and X.

The basal lamina of the epithelium contains type IV collagen. The corneal epithelium is chemically made up of 70% water. The solids are nucleic acids, lipids, and proteins. There is high activity of the enzyme of glycolysis, kreb's cycle and ATP ase.

The main collagen of stroma is type I. Others include type II, III and V.The proteoglycan in the extra fibrillar matrix influence fibril diameter and orderly packing of stromal fibres. keratan sulphate is the major constituent in central stroma while chondroitin sulphate in peripheral cornea. The GAG play very important role in corneal hydration. The Descemets membrane consists of type IV collagen, with a high content of glycine, hydroxyl glycine and hydroxyproline.

PHYSIOLOGY OF CORNEA

The normal cornea is transparent and any change in this property interferes with the clarity of the retinal image. The anatomic peculiarities of the corneal structure, like

1. The uniformity and regularity in the arrangement of the epithelial cells
2. Closely packed corneal lamellae
3. Collagen fibres of uniform size running almost parallel to each other,
4. Absence of blood vessels-all contribute to the efficiency of cornea as an optical instrument.

The factors that contribute to preserve the relative dehydration of corneal tissue are

1. Anatomic integrity of the endothelium and epithelium
2. Electrolyte and osmotic equilibrium
3. Metabolism of the cornea.
4. Evaporation of water through anterior surface of the cornea.
5. Intra ocular pressure

METABOLISM OF CORNEA

Energy in the form of ATP is generated by the break-down of glucose in Glycolysis and KREB's cycle. Cornea obtains glucose mainly from the aqueous humour and also from the tears and limbal capillaries. 36 molecules of ATP are obtained from each molecule of glucose.

HEALING OF CORNEAL WOUNDS

Injury to cornea results in increased hydration and loss of transparency. Proper healing of wounds is needed to avoid formation of corneal scars or opacities.

The factors that determine the speed and type of wound healing in the cornea are

1. Anatomic location –limbal or central
2. Size of the wound
3. Layer of cornea involved-epithelium, stroma or endothelium
4. Associated bacterial, viral or fungal infection
5. Topical drugs administered

CENTRES OF CORNEA

There are certain points on the corneal surface which are important in topographical description

- **Geometric centre**

Point which is determined by the intersection of the greatest and least diameters of the cornea. The geometric centre may also be considered as that point on the cornea through which the central pupillary axis will pass.

- **Visual centre**

The point which is formed by the intersection of the visual axis with the anterior surface of the cornea.

- **Apical centre**

The geometric centre of the apex is determined by the intersection of the greatest and least diameters of the apical zone.

NERVE SUPPLY

The cornea is supplied by the ophthalmic division of the trigeminal nerve via the anterior ciliary nerves. There is also a supply

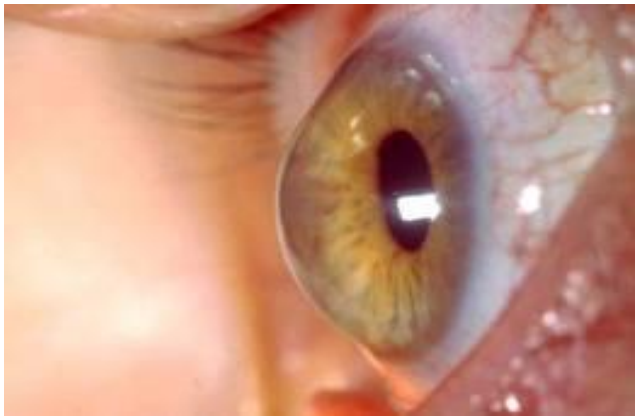
from the cervical sympathetic providing adrenergic fibres to limbus. The anterior ciliary nerves enter the sclera from the perichoroidal space, a short distance behind the limbus. They connect each other and with the conjunctival nerves, forming the pericorneal plexuses. The nerves pass into the cornea as 60-80 myelinated trunk at its junction with sclera. After having gone about 2-4mm they usually lose their myelin sheath and divide into two groups an anterior and a posterior.

The anterior fibres pass through the substance of the cornea and then form a plexus subjacent to the bowmans membrane. Having traversed the bowmans membrane the fibres connect to form a subepithelial plexus and end in the epithelial cells forming the intra epithelial plexus. The posterior part passes to the posterior part of cornea.

KERATOCONUS

Keratoconus is a progressive degenerative non inflammatory, thinning disorder causing irregular astigmatism of unknown cause.It has a teenage onset, usually bilateral but often asymmetric.

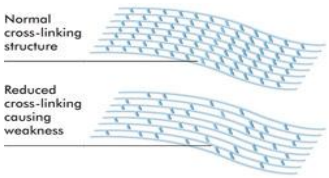
Keratoconus is a contraindication for most refractive surgeries so diagnosis of this condition is very critical. We should suspect keratoconus in any young patient with increasing myopic astigmatism, difficult to get 6/6 vision with refraction, decreased quality of vision due to diplopia, haloes, or ghost images.



PATHOGENESIS

The characteristic stromal thinning and loss of bowmans layer found in keratoconic cornea are associated with increased degenerative enzyme activities and decline in the enzyme inhibitors.

Increased levels of lysosomal enzymes like acid esterases , acid phosphatases, acidic lipase, cathepsins and matrix metalloproteinases -2. Inhibitors of these enzymes such as alpha 1-proteinase inhibitor, alpha 2 macroglobulin, tissue inhibitor of metalloproteinase 1 and 3 are decreased



ABNORMAL STROMAL MATRIX

Immunohistochemical studies showed that keratoconic corneas have decreased fibronectin, laminin, entactin, type IV and XII collagen and elevated levels of type III collagen, tenascin-c, fibrillin-1 and keratocan. Stromal lamellar slippage plays a significant role in keratoconus thinning and anterior protrusion.

GENETICS

Keratoconus is found in identical twins and multigenerational families. Most families show autosomal dominant inheritance with variable penetration. There are 10 different chromosomes (21,20q12,20p11-q11,18p,17,16q,15q,13,5q14.3-q21.1,3p14-q13,2p24) and three HLA antigens HLA-A26,B40,DR9 associated with keratoconus.

TRANSCRIPTION FACTORS

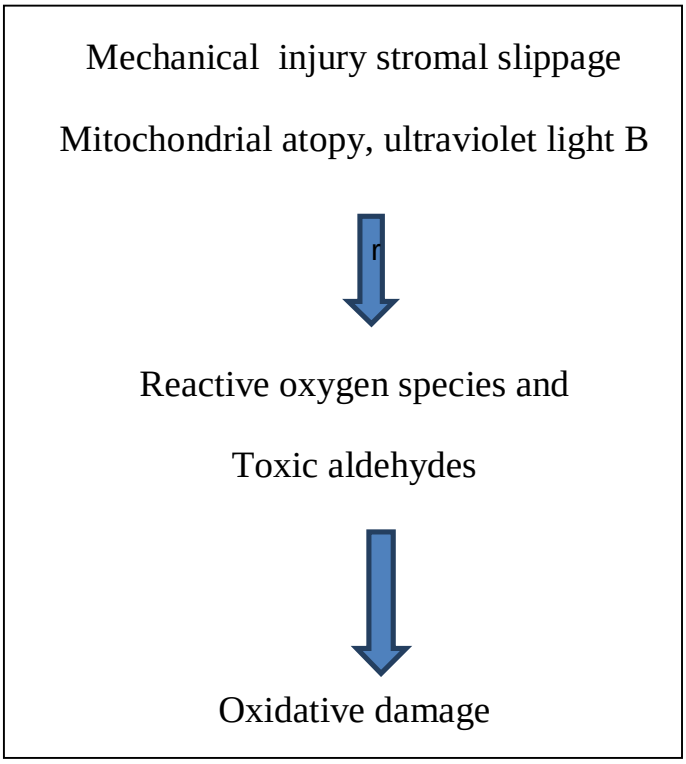
Two transcription factors, sp1 and kruppel like factor are elevated in keratoconic cornea and can repress the promoter activity of the alpha 1 proteinase inhibitor leading to lower protein levels. More recently, keratoconic corneas were shown to have elevated levels of the sp3 repressor short proteins.

APOPTOSIS

Apoptosis is a biological process of programmed cell death commonly associated with caspase dependent cascade.60% of keratoconic corneas have apoptotic stromal keratocytes . Apoptosis occur in the anterior stroma and in other layers. Keratoconic corneas express elevated levels of cathepsins which represent a caspase independent pathway for apoptosis.

OXIDATIVE DAMAGE

1. Increased oxidative , cytotoxic byproducts.
2. Abnormalities of corneal antioxidant which are responsible for elimination of ROS and toxic aldehydes
3. Defect in SOD1 gene, an antioxidant enzyme.
4. Increased mitochondrial DNA damage.



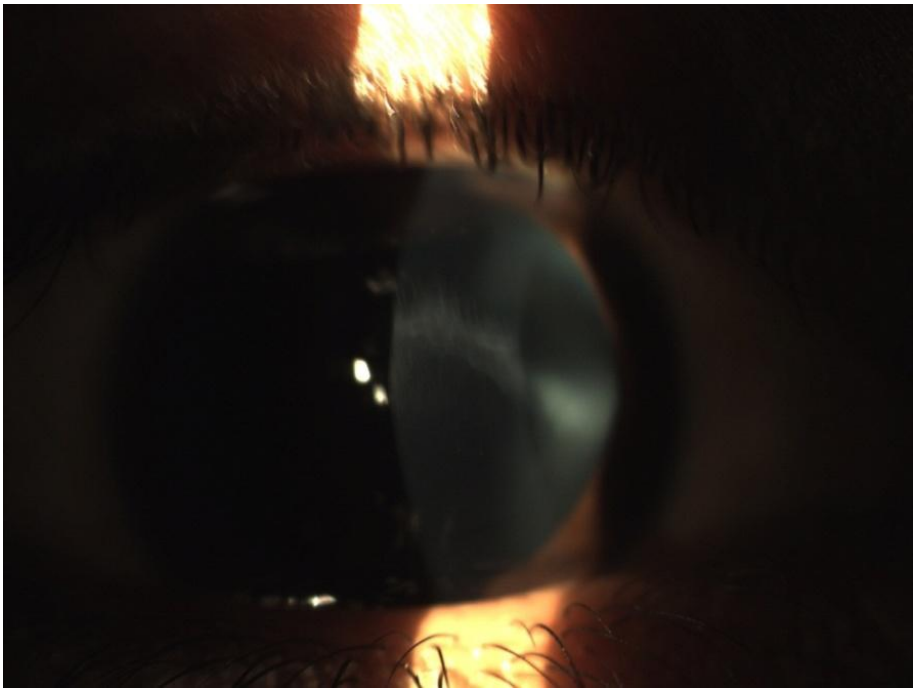
Keratoconus typically progresses and stabilise in the fourth decade.

keratoconus is associated with other conditions like

SYSTEMIC ASSOCIATIONS	**OCULAR DISORDERS**
Marfans syndrome	Retinitis pigmentosa
Ehlers –danlos syndrome	Blue sclera
Osteogenesis imperfecta	Congenital cataract
Congenital hip dysplasia	Aniridia
Oculodento digital syndrome	Posterior polymorphous dystrophy
Riegers syndrome	Fuch ‘s dystrophy
Downs syndrome	Osteogenesisimperfecta
Crouzon’s syndrome	Posterior polymorphous dystrophy
Hypothyroidism	Atopy

CLINICAL FEATURES

SLIT LAMP SIGNS



The diagnosis of keratoconus is based on slit lamp examination. One of the most useful slit lamp signs is focal thinning at the corneal apex.The area of maximal thinning corresponds to the area of maximal ectasia. Abnormal topography in the presence of normal slit lamp examination is keratoconus suspect also called “Forme Fruste” keratoconus.

VOGT'S STRIAE

Vogt's striae are a sign of corneal stretching and protrusion. These are vertical folds at the level of posterior stroma and descemets membrane in the area of maximal thinning and best seen with a wide slit lamp beam.These stress lines disappear with gentle pressure at the limbus and return once pressure is released.

FLEISCHER RING

Fleischer's iron ring is a sign of keratoconus and is due to accumulation of ferritin particles in corneal basal epithelial cells.The ring of iron deposition in the corneal basal epithelium surrounds part or all of the cone.It is seen with broad slit lamp beam and the cobalt blue light.

MUNSON SIGN

V shaped protrusion of the lower lid observed in downgaze caused by ectatic cornea.

RIZZUTI 'S SIGN

Light focussed on the nasal limbus with lateral illumination. The optics of the cone refracts the incoming light back onto nasal sclera.

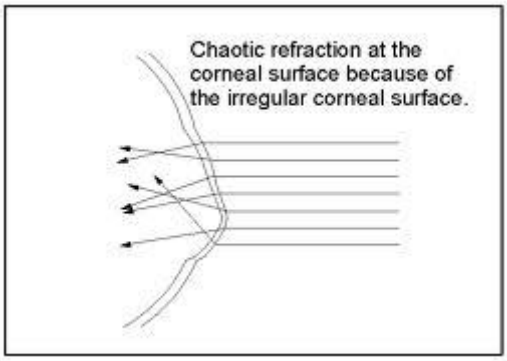
CHARLEUX OIL DROPLET SIGN

In ophthalmoscopy, dark round shadow in the corneal mid periphery is seen due to total internal reflection of light surrounding the red reflex.

RETINOSCOPY SIGNS

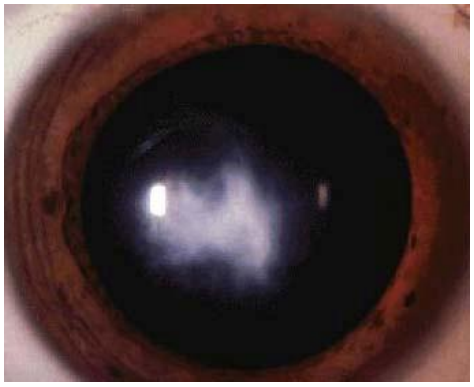
The scissoring effect of the retinal reflex seen with manual retinoscopy is largely diagnostic of Keratoconus.The optical path length

through the eye is longer along the direction through cone apex,compared to the surrounding region. The retinoscopic reflex will tend to appear distorted and flash unequally as light streak from the retinoscope is passed through the pupil of the patient.



CORNEAL HYDROPS

A manifestation of advanced keratoconus where there is sudden loss of vision associated with pain caused by breaks in descemets.A marked corneal edema with fluid clefts in stroma. It resolves over weeks resulting in scarring and flattening with or without corneal neovascularisation.



Significant scarring with reticular pattern may develop in advanced keratoconus.

KERATOMETER or OPHTHALMOMETER

“ Keratometry” is the procedure to measure the radius of curvature of the anterior surface of the cornea in different meridians. The instrument used is the keratometer consists of an illuminated target, a

fixation device for the eye being examined, a telescope to magnify the corneal image and a doubling device to align and indirectly measure the images.

PRINCIPLE

Keratometry makes use of the first purkinje image. The corneal surface acts as convex mirror so that the size of the image produced varies with the curvature, greater the curvature of the mirror, the smaller the image. The radius of curvature is deduced by the following formula:

$$r = \frac{2dxA'B'}{AB}$$

Where **r** = radius of the cornea in mm

d = distance of the object from the eye

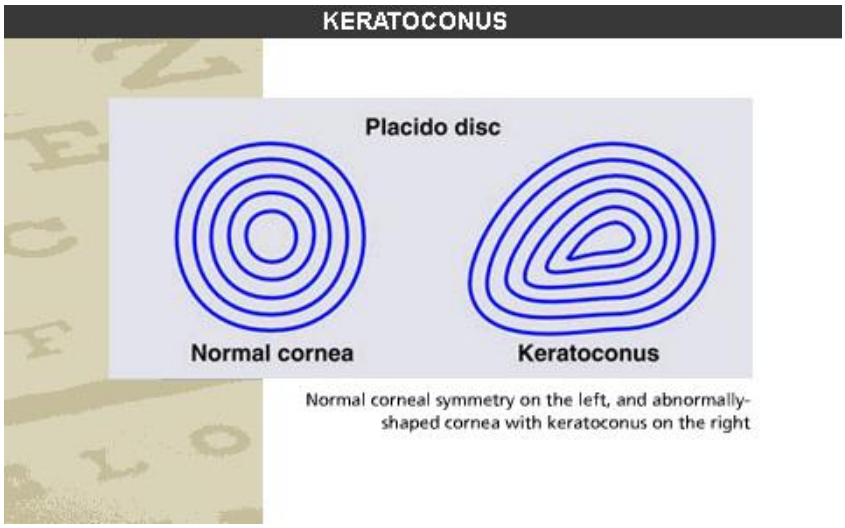
A'B' = image size

AB = object size.

KERATOSCOPIC SIGNS

Keratoscopy is the precursor to modern corneal topography. It uses a pattern of concentric rings (mires) called a placido disc with approximately 9 alternating bright and dark rings. The rings are reflected off the anterior corneal surface via purkinje image number one and

viewed directly by the clinician. The pattern of the rings is assessed for diagnosing irregular astigmatism or keratoconus. The rings appear to be thin and tightly squeezed in the area of steep cornea and broadly dispersed wherever the curvature was flat.



PHOTOKERATOSCOPY

Photokeratoscopy is same as keratoscope except that the placido disc is back illuminated with the strobe flash and a camera replaces the clinician eye at the viewing port that takes a picture of the reflected mire pattern.

In the spherical cornea, the rings appeared to be circular, with corneal astigmatism, the rings appeared to be oval with short axis corresponding to the steep meridian. In keratoconus, the rings are distorted and more grouped in the region of the cone.

METHODS OF MEASUREMENT OF CORNEAL CURVATURE

Falls into 2 categories.

1. Based on the principle of reflection
2. Based on the principle of projection

1. REFLECTION based

They measure the slope of the corneal surface and use the information to calculate radius of curvature and power. It does not measure elevation

Ex. Keratometer and videokeratoscope

2. PROJECTION based

They measure the true corneal shape in terms of elevation from which slope, power and curvature can be calculated

Ex. Slit photography, rasterstereography, laser interferometry.

CORNEAL TOPOGRAPHY

Corneal topography--also known as videokeratography -shows a significant advance in the measurement of corneal curvature over keratometry. It evaluates 8,000 to 10,000 specific points across the entire

corneal surface. Keratometers measure only four data points within the cornea's central 4mm

Topography provides both a qualitative and quantitative evaluation of corneal curvature. It has concentric rings, which project onto the cornea to create a virtual image. The device compares this image to the target size, and the computer then calculates the corneal curvature. Since cornea is aspheric, the radius of curvature is not equal at all points. The two most common maps are

- ***Axial map.*** Also called the "power" or "sagittal" map. It shows variations in corneal curvature as projections and uses colors to represent dioptric values. Warm colors such as red and orange show steeper areas; cool colors such as blue and green denote the flatter areas.

Color scales used

Color	Power	
Red	48.0	Steep
Orange/yellow	45.0	
Yellow/green	43.5	average
Green/light blue	42.0	
Blue	39.0	Flat

The axial map gives a global view of the corneal curvature as a whole.

- ***Tangential map.*** Also known as instantaneous, local, or "true" map, it also displays the cornea, using colors to represent changes in dioptric value, but it accurately determine the peripheral corneal configuration. The tangential map recognizes sharp power transitions more easily than the axial maps. Tangential maps yield smaller patterns that are more centrally located.

There are two other types of corneal topography maps:

- ***Elevation map.*** An elevation map shows the measured height from which the corneal curvature varies from reference surface. Warm colors shows points that are higher than the reference surface; cool colors designate lower points. Normally any elevation of the front surface should not exceed +12microns and elevation of the back surface should not exceed +17microns. This map is most useful in predicting fluorescein patterns with rigid lenses

- ***Refractive map.*** This utilizes the measured dioptric power and applies Snell's law to describe the cornea's actual refractive power.

The central portion of the refractive map is most important. This area overlies the pupil, so aberrations here almost invariably impact visual performance.

Scales - Label on the scale gives the type of measurement which is displayed.

ABSOLUTE SCALE

There is a fixed color coding system. The same color always represent the same curvatures in powers. The allocation of powers is related to the distribution of corneal powers.It uses a scale of 1.5D intervals and can miss subtle local changes in early keratoconus.

NORMALISED SCALE

It uses a set number of colours which are adjusted to fill the range of dioptric values for that single map.when comparing eyes with very different curvature readings.It is best to use normalized (relative) maps when evaluating one particular eye, and use standard maps when comparing two different eyes or comparing the same eye over time. A normalised scale has the advantage over the absolute scale of using narrower steps of 0.5D between the contours which provides more detailed description of corneal surface.

Absolute scale	Normalised scale
Standardised	Non standardised
Good for comparison	Comparison is difficult
Large step sizes	Small steps
Low resolution	High resolution
Wide range of powers	Narrow range of powers
Good screening	Subtle features can be detected
Good for gross pathology	Good for detail

Clinical Indications

Topography is indicated in many clinical situations.

- **Keratoconus and pellucid marginal degeneration** exhibit corneal steepening before any biomicroscopic signs are evident. In keratoconus, the color maps provide information of the location, size and curvature of the cone's apex, and help in follow the patient for the progression of the disease..
- **Post-RK or LASIK,** in which the central cornea flattens relative to the periphery, potentially resulting in residual refractive error and irregular astigmatism;

- **Advanced keratoconus,** in which the central and peripheral curves of the lens are critical to accommodate the protruding cone.

KERATOCONUS PREDICTION INDICES

1.	Sim K1	5.	Opposite sector index (OSI)
2.	Sim k2	6.	Centre surround index (CSI)
3.	SAI	7.	Irregular astigmatism index (IAI)
4.	Analysed area (AA)	8.	Differential sector index(DSI)

KISA INDEX

The KISA INDEX quantifies the topographic features in patients with clinical keratoconus. It is obtained by

1. K value, an expression of central corneal steepening.

2. I-S value, an expression of inferior superior dioptric asymmetry.

3. AST INDICES, which quantify the degree of regular Corneal astigmatism. (SIMK1-SIMK2)

4. SRAX index- an expression of irregular astigmatism in keratoconus.

KISA %= K x I-Sx AST x SRAX x 100 / 300

I-S Rabinovich law

First the flat axis is identified on the sagittal curvature map. The curvature power is measured in five points above the flat axis., 3mm from the corneal centre and 30 degree apart. The same is repeated below the flat axis. The superior is subtracted from the inferior. The normal value is positive and less than +2 . It is abnormal when values are more than +2.

Kerartoconus Topographic Indices According to Rowsey's rule of2

Cornea over 2 diopters steeper than 45

Cornea over 2 diopters steeper than fellow

Cornea over 2 diopters I-S asymmetry.

SRAX law - it is skewed steepest Radial Axis Index. It is an index of angulation between the lower and upper segments. More than 22 degree is a risk factor.

Rabinowitz diagnostic criteria for keratoconus

1. K value of 47.2 D or greater
2. I – S value of 1.4 D or greater
3. KISA index

- 60 – 100% represents keratoconus suspect
- More than 100% highly suggestive of keratoconus.

There are several patterns of corneal curvature.

1. Round, where the steepest part of cornea is round but decentered.
2. Oval, where the steepest part of cornea is oval and decentered.
3. Superior steep , where the steepest part of the cornea is localised in the upper part of cornea.
4. Inferior steep- where the steepest part of the cornea is inferior to apex.
5. Irregular- where the corneal surface takes no particular shape.
6. Symmetrical bow tie- indicative of normal astigmatism.
7. Skewed radial axis pattern
8. Smiling face pattern
9. Junctional type
10. Vortex type

Axial power patterns of the anterior corneal surface.

Identified pattern	**Percent**
Round	6.52
Oval	26.07
Symmetric bow tie	39.13
Asymmetric bow tie	23.91
Irregular	4.53

With keratoconus and keratoectasia, there are **four main types** of patterns.

1. Lobes of the bow –tie may be unequal in size, but lobes are not bent.
2. Lobes of bow-tie may be equal in area and are not bent.
3. Lobes may be equal in size and have the same color in each lobe but they may show distortion in the form of bend along the axis called lazy - 8 pattern.
4. Lobes of bow tie may be unequally sized with a bent axis and curvature in lobes may be equal to each other.

When steepening is localised into a round central bull's eye cone pattern with the steepest curvature near the centre it is highly indicative of **central keratoconus.**

MEASUREMENT OF ASPHERICITY

There is a difference between the centre of curvature between the steepest cornea and the flat cornea. This is known as asphericity. From the eccentricity value, Q value can be found.

Q = O, when the cornea is spherical.

Q = negative, when the cornea is prolate

Q = positive when the cornea is oblate

Q = -2 in advanced keratoconus

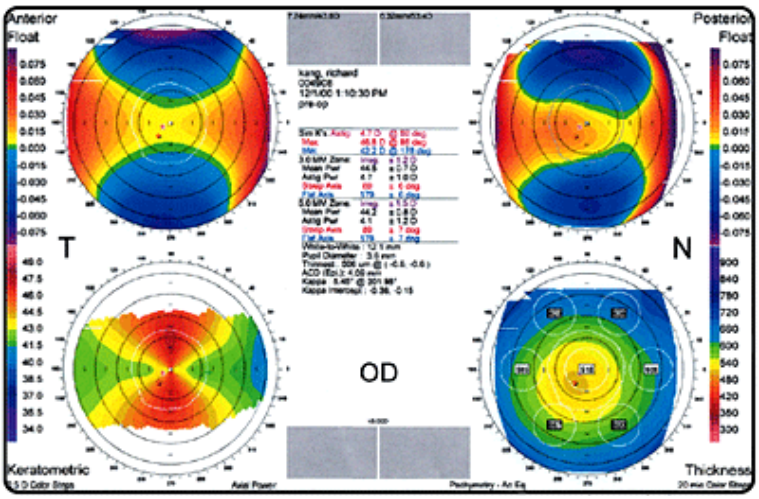
Q = -1 in moderate keratoconus

Q = -0.5 , no spherical aberration found

Q = -0.26 to -0.35 in most normal corneas.

ORBSCAN

The ORBSCAN II is a hybrid system which combines a projectile slit scanning device with a reflective placido technique. During the 1.5 second examinations, two slit scanning lamps project a series of 40 slit beams angled at 45 degrees. The images are represented as color maps including curvature maps , anterior and posterior elevation maps, and pachymetry maps.



Orbscan red flags for keratoconus or keratoconus suspects

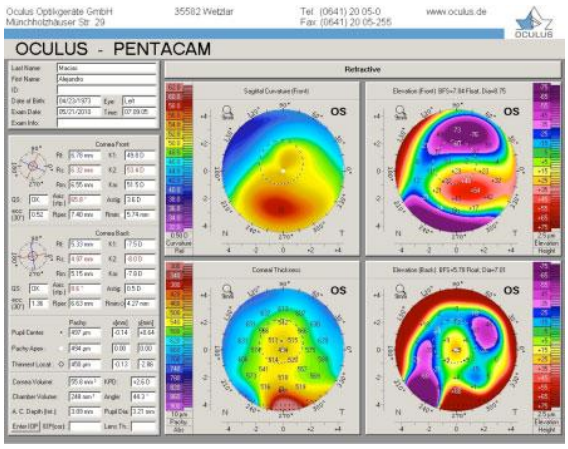
- Posterior float > 50 µm
- Pachymetry thinnest < 500 µm concentric with posterior float
- Best fit sphere steeper than 55 D
- Inferior pachymetry < 20 µm thicker than central pachymetry
- Thinnest point > 2.5 mm from center or > 30 µm thinner than central thickness
- Anterior float > 15 µm
- Corneal power < 40 D or > 48 D
- Keratometric mean power map > 45.50 D steepest point
- Irregularity index > 1.50 D at 3 mm or > 2 D at 5 mm
- Roush criteria: Posterior float difference steep-flat > 100 µm

Source: Tullo WJ; adapted from Karpecki PM

PENTACAM

The pentacam uses rotating Scheimpflug imaging technology to generate a complex image of the anterior segment of the eye within 2 secs. A rotational blue slit light of fixation centre is directed towards the cornea. The camera is laterally located and captures all the media the light slit can penetrate and reach. Topography and pachymetry of the entire anterior and posterior surface of the cornea from limbus and limbus is calculated and displayed. It contains the saggital curvature, front elevation, back elevation and corneal thickness map.

It also measures the anterior chamber angle, depth, volume and anterior and posterior surface of the lens and lens densitometry.



In the 4mm centre circle, the thickness of the lowest point is 30mm more than the upper point. Curvature power of the lower point is 1.5D more than the upper point.

FORME FRUSTE KERATOCONUS

Forme fruste keratoconus has no identifiable slit lamp signs, but topography shows a cone pattern. It is diagnosed only by topography. It may or may not exhibit astigmatism on manifest refraction and the visual acuity may be normal. Another entity called “inferior steepening” is a risk factor for Lasik surgery. It is best diagnosed by pentacam by an elevated elevation map on the posterior surface of the cornea.

AGARWAL CRITERIA TO DIAGNOSE POSTERIOR CORNEAL ELEVATION

1. Ratio of the radii of anterior and posterior curvature of the cornea more than 1.2
2. Posterior best fit sphere more than 52 D
3. Difference between the thickest and thinnest corneal pachymetry more than 100 micons
4. Elevation of posterior corneal surface more than 45 microns.

CORNEAL ECTASIA FOLLOWING LASIK

Corneal refractive surgery alters the shape, thickness , curvature and tensile strength of the cornea. Keratocyte density is greatest in the anterior 10% of the stroma and lowest in the posterior stroma. So tensile

strength of the cornea is maximum in the anterior part. surgery on normal cornea decreases the tensile strength by 13% after PRK and 27% after LASIK. the elastic modulus of the keratoconic cornea is 2.5 times less than normal cornea.

The incidence of post operative ectasia following Lasik range from 0.04% to 0.6%. The early indicators of post operative ectasia includes both reducing corneal thickness and inferior steepening. The increasing posterior float values in pentacam is an early indicator of keratectasia.

RISK FACTORS FOR ECTASIA

1. Keratoconus.
2. Pellucid marginal degeneration
3. Forme fruste keratoconus.
4. Low residual bed thickness
5. Low preoperative corneal thickness
6. High myopia.

THE ECTASIA RISK SCORE SYSTEM

Pattern	4	3	2	1	0
Topo	Abnormal/ SRAX	Infr steepening		Asymmetrical bow tie	normal
RSB	<240	240-259	260-279	280-299	>300
Age		18-21	22-25	26-29	>30
CCT	<450	451-480	481-510		>510
MRSE	>14 D	12 to 14 D	10 to 12D	8 to 10 D	Less than 8

WAVEFRONT ABERROMETRY MAPS

Vertical coma is typically high in keratoconus. The central keratoconus will not be readily detected with aberrometry.

PACHYMETRY

It is the measure of corneal thickness. There are three methods of measuring corneal thickness.

1. Specular microscope
2. Optical pachymetry
3. Ultrasonic pachymetry.

DIFFERENTIAL DIAGNOSIS

1. Pellucid marginal degeneration
2. Keratoglobus
3. Posterior keratoconus
4. Terriens marginal degeneration

In **Pellucid marginal degeneration**, the area of maximal thinning is typically below the area of maximal ectasia. The area of thinning usually extends from the 4 " 0 clock position to 8" 0 position and is 1-2mm central to inferior limbus. There is no sex or racial predisposition. These cornea are clear , avascular, without scarring or iron ring.

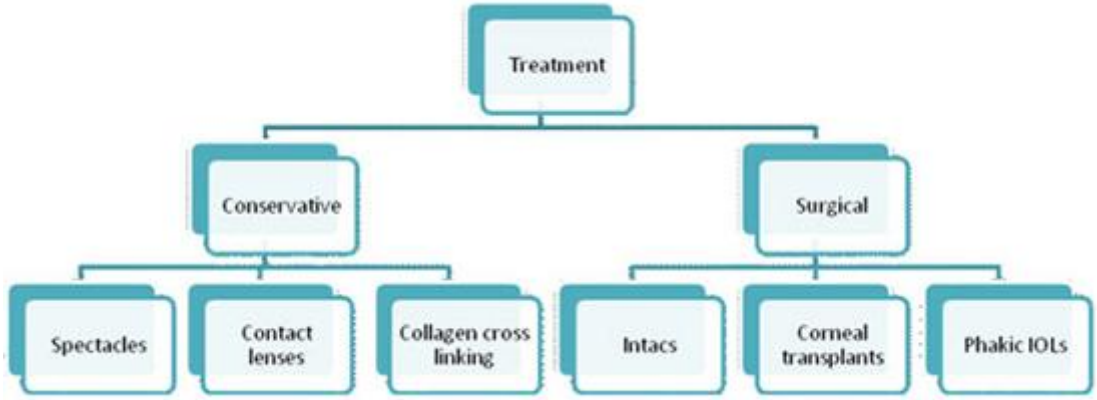
In **keratoglobus** there is limbal to limbal thinning and ectasia and the maximum thinning is in the mid periphery. It is a true ectasia with corneal stretching resulting in increased corneal surface area.

Posterior keratoconus, is a mild form of anterior dysgenesis in which there is localised area of increased posterior corneal curvature resulting in thinning with or without scarring. The anterior surface is minimally involved. It resembles megalocornea except that the cornea is thinned uniformily particularly in the periphery.

Terriens marginal degeneration- it affects both the superior and inferior cornea, associated with lipid deposition and vascular invasion.

MANAGEMENT

As the cornea is irregularly shaped in keratoconus, each cornea needs to be individually treated. Patients may benefit from



1. Spectacles
2. Contact lenses
3. Corneal Collagen Cross linking procedure
4. Intacs
5. Implantable contact lenses
6. Surgical management

SPECTACLES

Spectacles give a reasonable acuity in low grades of keratoconus, when there is limited irregular astigmatism. If the cone is advanced, spectacles may not help much because of the high irregular astigmatism.

CONTACT LENSES

Corneal geometry has typically been the primary determining factor in the decision of type of lens that is fitted for keratoconus. Wavefront technology helps in finding the higher order aberrations. The individual immune response to the normal environment is an indicator, how the eye will respond to contact lens wearing for 14 to 16 hours.

CONTACT LENSES

• soft toric lenses • RGP lenses • Rose-K lenses	• piggy back lenses • soft permeable hybrid lenses • boston scleral contact lenses • Kerasoft contact lenses

There are two main category of soft lenses. Simple toric design and complex aspheric designs. The choice of contact lens often depends on the severity of keratoconus.

RGP LENSES

They are the mainstay of treatment of keratoconus. The refractive index is similar to that of cornea so little refraction takes place at the corneal surface. The usual best fit technique is used for both soft and RGP lenses.

The “3 point touch” is the classical design used to fit keratoconus patients when the cone is central.It refers to support provided for the lens by an area of central bearing and two other areas at the corneal mid periphery.The apical clearance designs vault over the corneal vertex suited for small central or paracentral cones. Large flat lens designs are used in displaced apexes.

ROSE-K lenses

There are three lens designs to fit all corneal shapes.

- ROSE K2
- ROSE K2IC
- ROSE K2 post graft

ROSE K2 lens fits all stages of keratoconus because of unique lens design that changes as the base curve steepens. It uses flexible edge lift system and aspheric optics to get a best fit.

The base curve range from

- 4.3 to 8.6mm in K2
- 5.7 to 9.3mm in K2IC and K2 post graft

The diameters include

- 7.9 to 10.4mm in K2
- 9.4 to 12 mm in K2IC and K2 postgraft

ALL ROSE-K lenses dispensed use the standard edge, standard flat, or standard steep to achieve the desired peripheral fit. With ROSE K2 lenses, the flexible edge lift system is available in 5 different values, standard, standard steep , standard flat, double steep or double flat edge lift.

PIGGY BACK LENSES

Piggy back lenses are the use of rigid lens over a hydrogel lens increases comfort resulting in adequate good vision. The combination of hard lens and soft lens results in corneal edema due to hypoxia and neovascularisation.

HYBRID LENSES

They are combination of hard and soft lenses. The rigid centre optimises vision while the soft outer holds the lens in place better than a rigid lens. A high Dk hybrid lens called clearcone lenses fit a broad spectrum of keratoconus patients including oval cones, advanced central cones, decentered cones, keratoglobus and PMD.

SCLERAL CONTACT LENSES

These lenses are supported by the sclera and the positional stability are independentent of distorted corneal topography. They do not

contact with corneal surface. The lenses create an artificial tear filled space over the cornea.It consist of a central optic that vault over the cornea and a haptic which rest on sclera.

INTACS

These are C- shaped PMMA implants inserted to pockets created in the deep stroma of the mid peripheral cornea. The creation of scleral pockets can be done by the femtosecond laser. It is useful in patients whose cornea is so steep that contact lenses were unstable for their comfort.

The goal of intacs is to improve vision by reducing irregular corneal shape caused by cone and correct the refractive error in patients with myopia, keratoconus and ectasia.

Based on the principle of the “hammock effect” they redistribute the bio-mechanical stress exerted on the cornea by the aqueous and prevent further steepening of the cornea. Intacs are available in various sizes from 0.250 to 0.450mm which are chosen according to the refractive error and thickness of the patient. They correct vision ranging from +1.00 to -8.00 D.

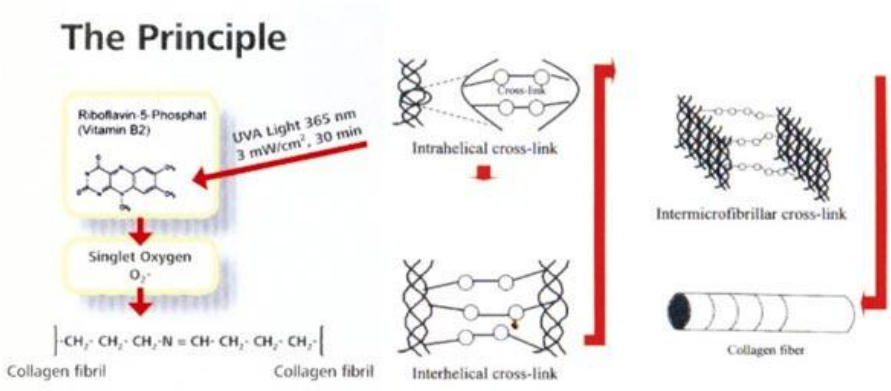
It is contraindicated in uncontrolled autoimmune disorder, collagen vascular disorder, immunodeficiency diseases.Advantage includes the fact that there is no removal of corneal tissue, changes are reversible when removed.,the central cornea remains undisturbed. Post operative complications include ring segment extrusion or migration, corneal vascularization and infiltrates along the channel, under or overcorrection.

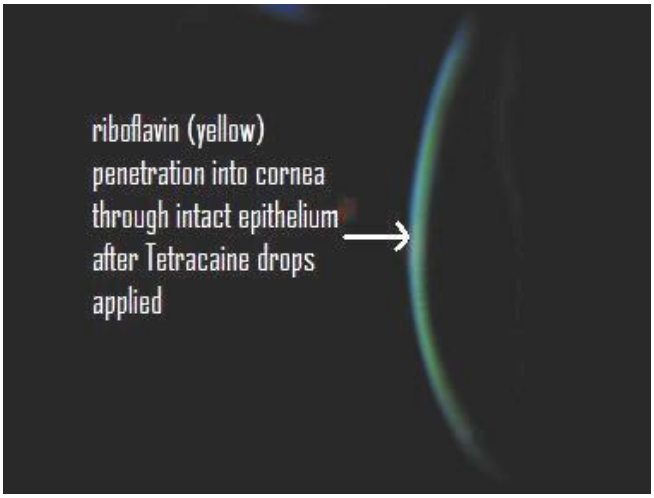
CORNEAL COLLAGEN CROSSLINKING PROCEDURE

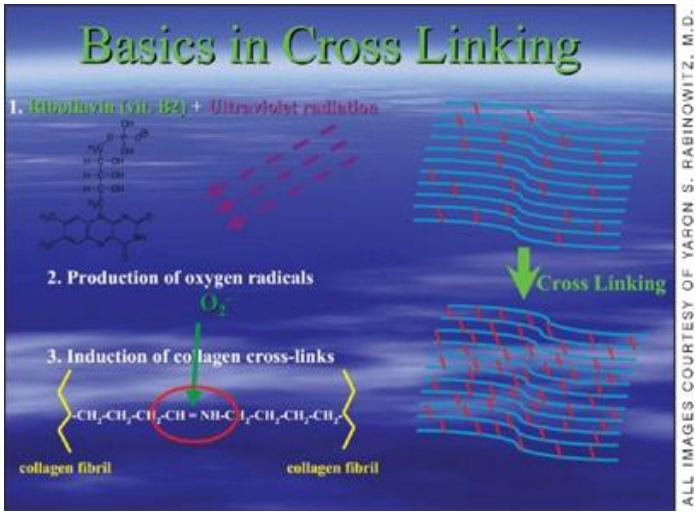
Crosslinking of human collagen is a physiological process. Corneal Collagen Crosslinking also known as C3R/CCL/CxL is a new approach to increase the mechanical and chemical stability of corneal tissue. The primary aim of the treatment is to create additional chemical bonds inside the corneal stroma by means of highly localised photopolymerization while minimising exposure to the surrounding structure of the eye

MECHANISM OF C3-R

Riboflavin eye drops are applied to the cornea which is activated by UVA at 370nm . The photosenstizer riboflavin is excited into its triplet state generating reactive oxygen species (ROS) which is mainly singlet oxygen and to a much less degree superoxide anion radicals. The ROS can further react with various molecules including chemical covalent bonds bridging amino groups collagen fibrils/type II photochemical reaction. The wavelength of 370nm of UVA is chosen because of an absorption peak of riboflavin at this wavelength.







INDICATION FOR C3-R

Progressive keratoconus

Iatrogenic post refractive keratectasia

Pellucid marginal degeneration.

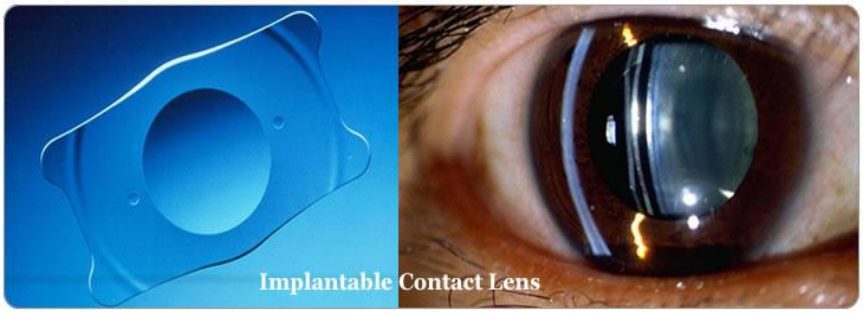
PARAMETERS FOR C3R treatment

- Disorder should be progressive in nature.
- Thinnest corneal pachymetry higher than 400um
- No central corneal scarring
- Maximum corneal corneal curvature not exceeding 62D

PRE OPERATIVE WORK UP

- Visual acuity measurement (UCVA, BCVA, contrast sensitivity)
- Intra ocular pressure measurement
- Detailed slit lamp examination specially for vogt's striae, Fleischer ring, corneal scarring
- Slit lamp photographs of corneal changes
- Pentacam evaluation of central corneal thickness and thinnest pachymetry
- Corneal topography
- OCT examination

IMPLANTABLE CONTACT LENSES



The implantable contact lens is a posterior chamber phakic IOL made of collamer which has become a preferred modality for correction of high myopia and for patients with thin corneas.

SURGICAL MANAGEMENT OF KERATOCONUS

Visual impairment because of scarring and contact lens failure are indications for surgical intervention to restore corneal anatomy. Penetrating keratoplasty is a safe and effective management of keratoconus.

A better understanding of the surgical anatomy of the cornea has superheaded the procedure of lamellar keratoplasty. Deep anterior lamellar keratoplasty is indicated in eyes where the pathology spares the endothelium. DALK is a technique where a plane of cleavage is created between the descemets membrane and corneal stroma. A donor corneal button, denuded of its DM, is then sutured to the recipient. The most common indication of DALK is keratoconus. A best corrected visual acuity of 6/12 has been repoted in 77 to 92% of keratoconus patient after DALK. Since the donor endothelium is not transplanted, the criteria for tissue selection is less stringent. This procedure has an optical clarity nearly as good as that of the penetrating graft and has less complications like intraocular inflammations , anterior synechiae, endophthalmitis, or suprachoroidal haemorrhage. The retention of the host endothelium eliminates the risk of endothelial graft rejection.

PART II

AIM OF THE STUDY

To study the efficiency of Corneal Collagen Cross linking procedure in patients with progressive keratoconus and also to analyse the results of Epi- on and Epi- off procedures.

STUDY CENTRE

Regional Institute of Ophthalmology and Government

Ophthalmic Hospital, Egmore

DURATION OF THE STUDY

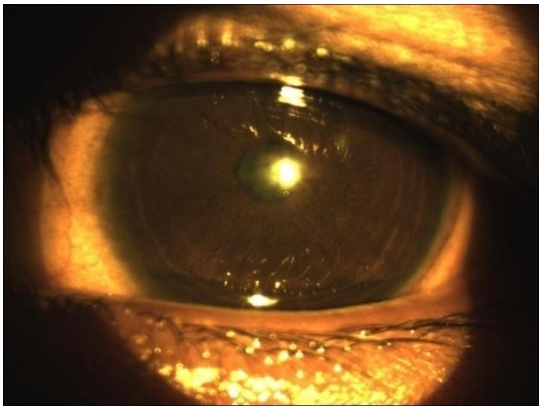
24 MONTHS (June 2010 to June 2012)

MATERIALS AND METHODS

Forty five eyes of forty patients with early progressive keratoconus who presented to Cornea services, RIOGOH, Egmore from 2010 to 2012 were analysed.

INCLUSION CRITERIA

Patients with progressive loss of vision, patient not improving with spectacles or contact lenses were included in the study.

- Values should be progressive
- Thinnest cornea should be more than **400** microns
- No central scarring
- Max corneal curvature should be less than **63D**

EXCLUSION CRITERIA

Patients with pachymetry less than 400 microns , patients with hydrops and vision at presentation less than 2/60 were not included in the study.

PRE OP EVALUATION

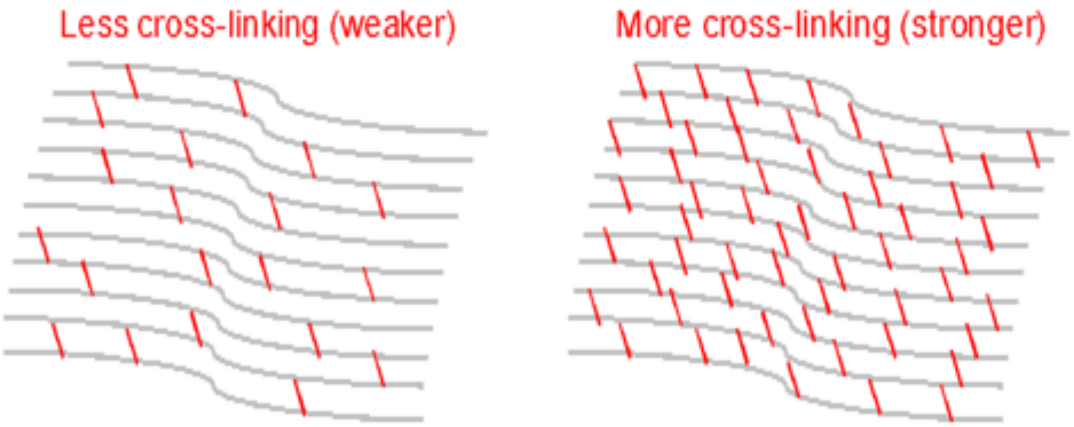
Evaluation of the patients included

1. Uncorrected visual acuity,
2. Best corrected visual acuity,
3. Thorough slit lamp examination,
4. Corneal topography,
5. Pachymetry.

All the selected patients were subjected to either Epi on or Epi off procedures. Patients with pachymetry more than 450 microns underwent Epi off procedures and pachymetry 400 to 450 by Epi on C3R procedure

PROCEDURE

C3R is a new approach to increase the mechanical and chemical stability of corneal tissue. The primary aim of the treatment is to create additional chemical bonds inside the corneal stroma by means of highly localised photopolymerisation while minimising exposure to surrounding structure of the eye.



After applying xylocaine drops, speculum is applied. 8mm of central corneal epithelium is removed to allow penetration of riboflavin into stroma. A disposable sterile solution of riboflavin 0.12% (in balanced salt solution) was instilled for every minute for 15 mins in order to prime the cornea for uv

irradiation. Then riboflavin was administered every 2 mins for a period of 30 mins as eye is exposed to UVA double diode at 370nm. The distance between UV delivery system and cornea should be 30mm so as to deliver dose of 3 mw/cm^2 (equal to 5.4J/cm^2). The eyes are thoroughly washed at the end of the procedure. Pad and bandage was applied. Plain antibiotics were given for two days. Then after examining the epithelium under slit lamp examination fluoromethalone 0.2% eye drops applied four times a day for four weeks, then tapered . We follow up the patients after one week with vision and AR subjective. Repeat topography was done at the end of 1 month, 6 months and 12 months.

RESULTS

Table 1 : - CORNEAL COLLAGEN CROSSLINKING PROCEDURES

S.no	procedure	45 eyes of 40 pts
1	EPI ON	14
2	EPI OFF	31

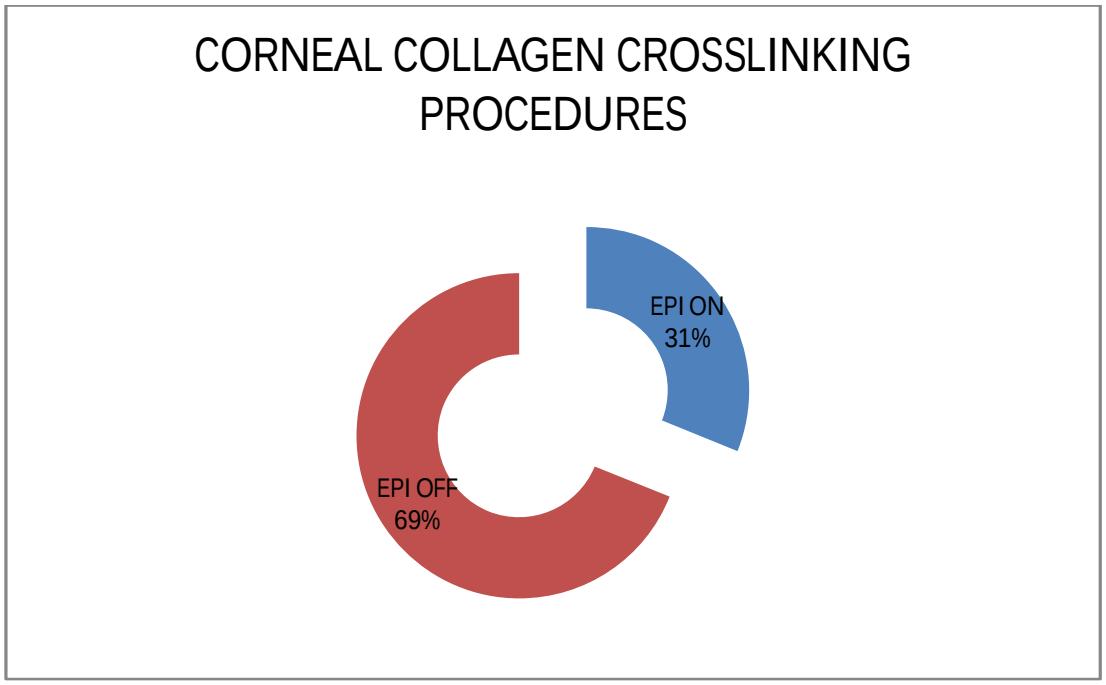


Table 2: AGE DISTRIBUTION

S.no	Age	Total pts (40)	Epi off (27)	Epi on (13)
1	10-15 yrs	10 (25%)	6 (22.2%)	4 (30.7%)
2	16-20 yrs	7 (17.5%)	4 (14.8%)	3 (23.1%)
3	21-25 yrs	11 (27.5%)	8 (29.6%)	3 (23.1%)
4	26-30 yrs	8 (20%)	6 (22.2%)	2 (15.4%)
5	More than 30 yrs	4 (10%)	3 (11.1%)	1 (7.7%)

Chi sq = 1.04, p = 0.9

AGE DISTRIBUTION

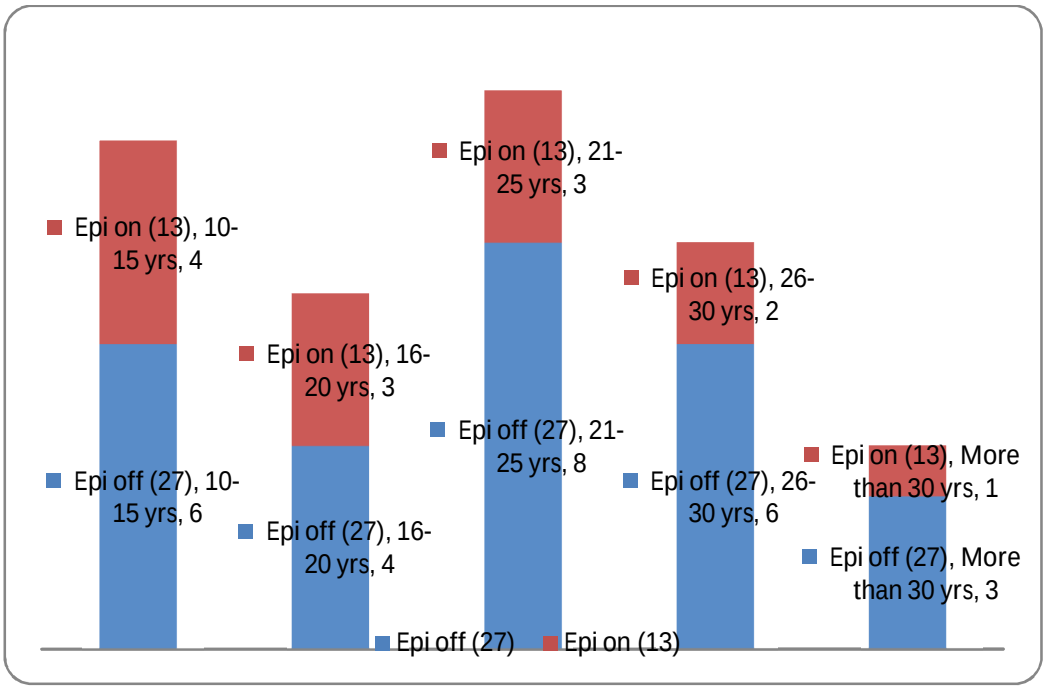


Table 3: SEX DISTRIBUTION

S.no	Sex	Total (40)	Epi off (27)	Epi on (13)
1	MALE	23 (57.5%)	17 (63%)	6 (46.2%)
2	FEMALE	17 (42.5%)	10 (37%)	7 (53.8%)

Chi sq = 1.01 p = 0.3

SEX DISTRIBUTION

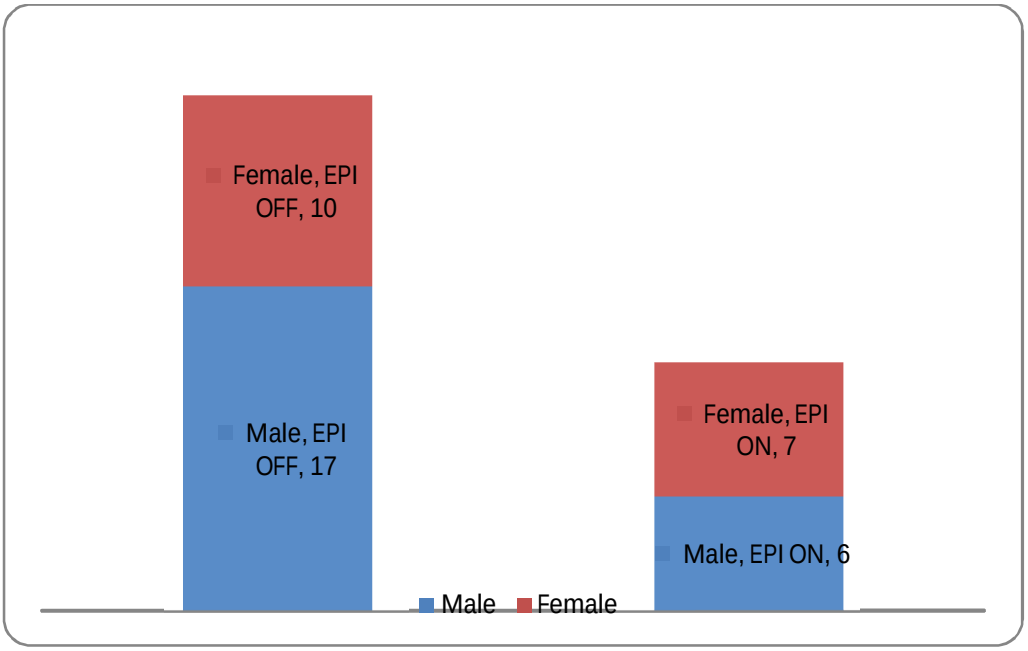


Table:4 LATERALITY

S.no	Laterality	Total (45) eyes	EPI OFF (31)	EPI ON (14)
1	RIGHT EYE	14	10	4
2	LEFT EYE	21	13	8
3	BOTH EYES	5 patients	4	1

Chi sq = 0.75 p = 0.6

LATERALITY

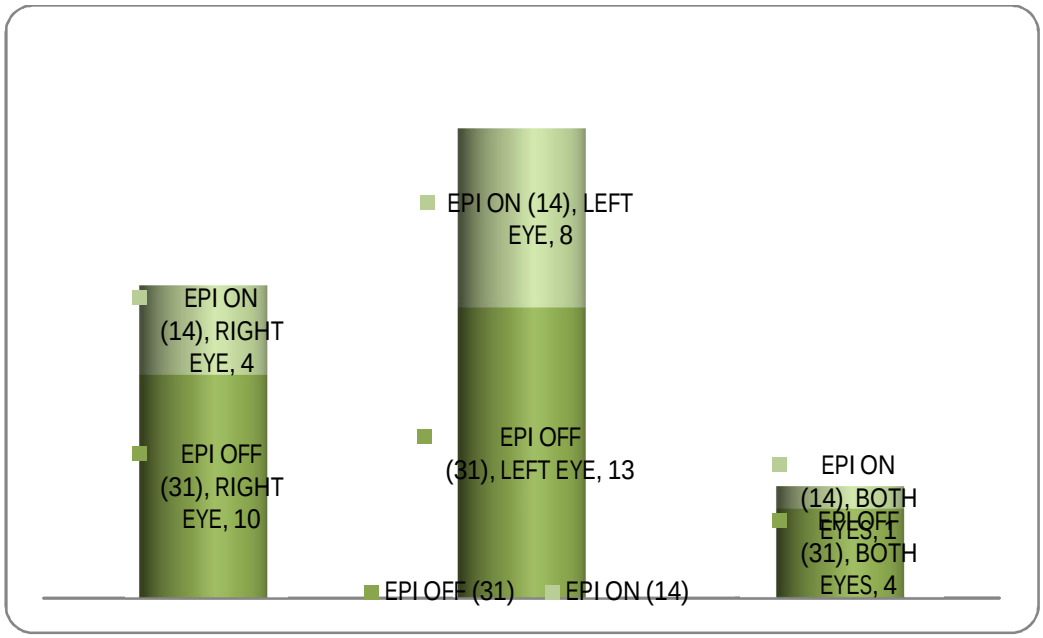


Table:5 K VALUES IN OUR SERIES

S.no	K value	Total N=45	EPI OFF (31)	EPI ON (14)
1	49 – 55 D	21	15	6
2	56– 60 D	15	10	5
3	More than 60 D	9	6	3

Chi sq = 0.12, p = 0.9

K VALUES IN OUR SERIES

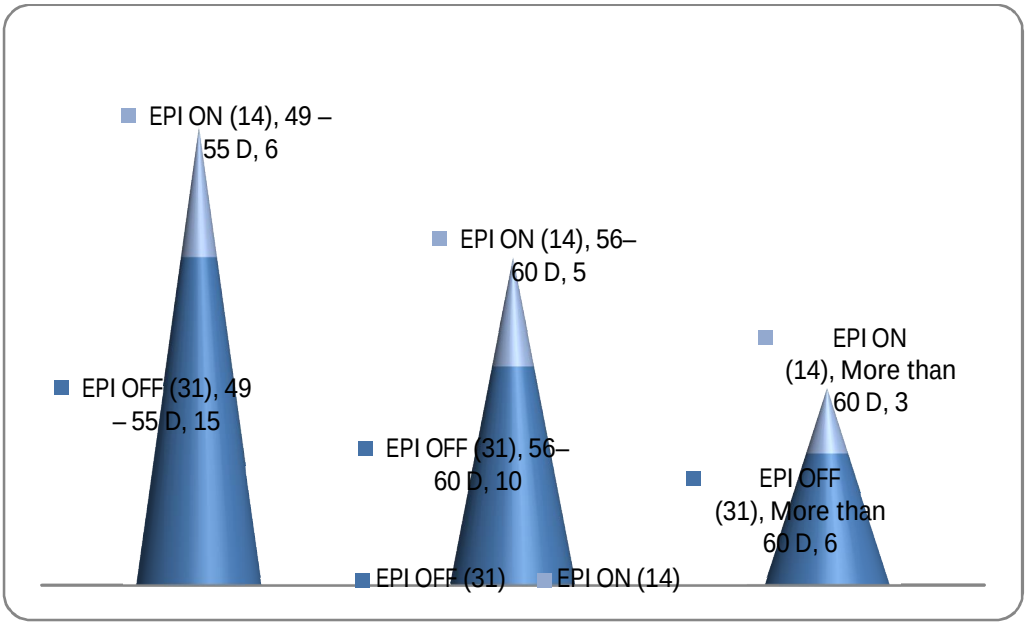
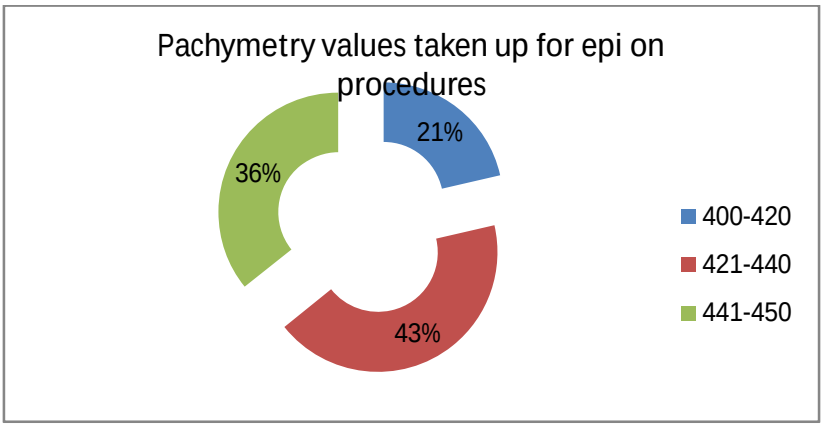


Table:6

Pachymetry values taken up for Epi on & Epi off procedures

S.no	Pachymetry	Epi off (31)	Epi on (14)
1	400-420 microns		3 (21%)
2	421-440 microns		6 (43%)
3	441-450 microns		5 36%)
4	450-480 microns	15 (48%)	
5	481-520 microns	10 (32%)	
6	More than 520 microns	6 (20%)	



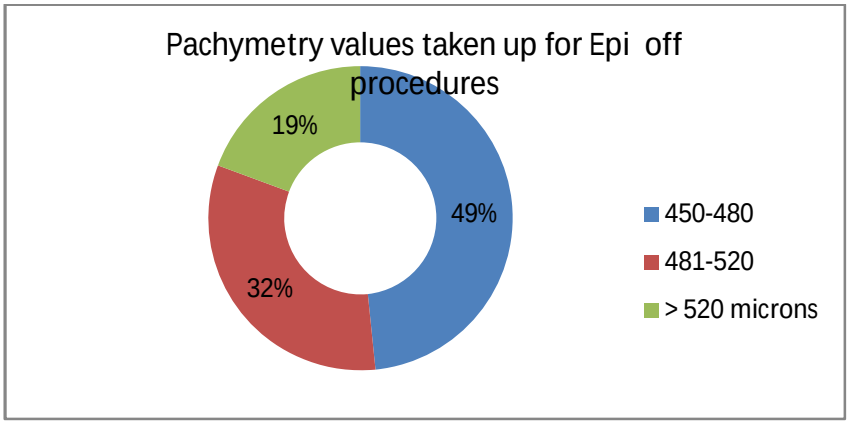


Table:7

Topo Response in EPI ON PROCEDURE

S.no	Topographically	EYES=14
1	Flattening	7 (50%)
2	Steepening	3 (21.4%)
3	Stable	4 (28.6%)

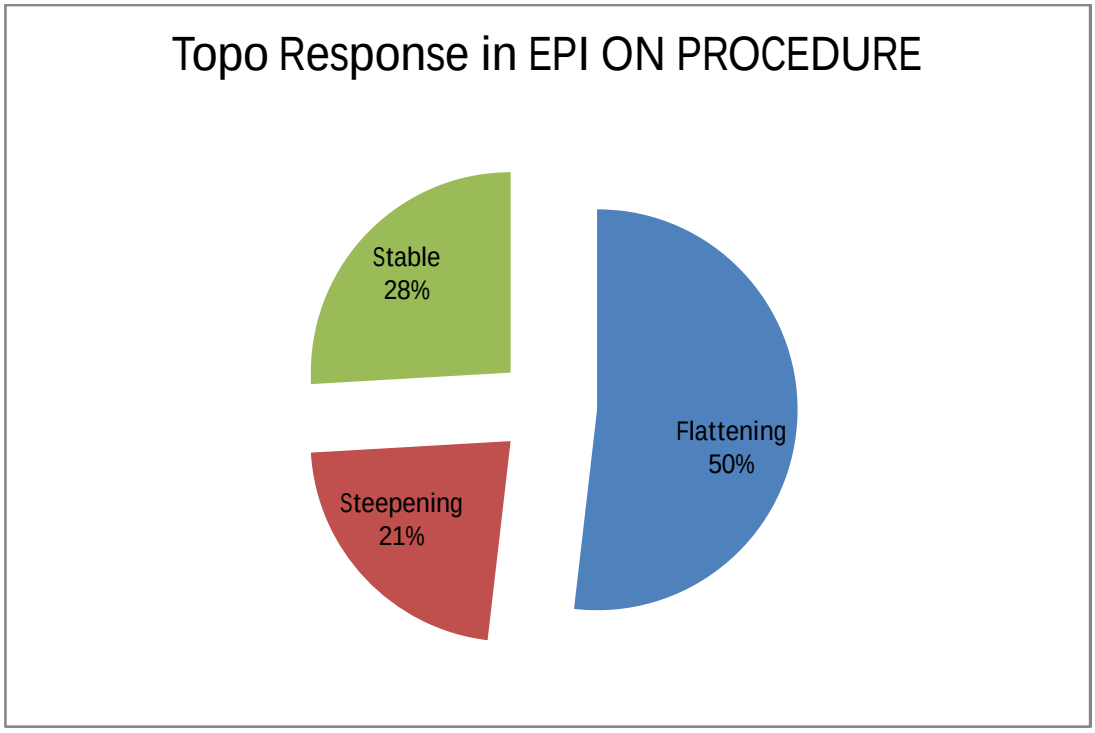


Table:8

Topo Response in EPI Off PROCEDURE

S.no	Topographically	EYES=31
1	Flattening	16 (52%)
2	Steepening	10 (32%)
3	Stable	5 (16%)

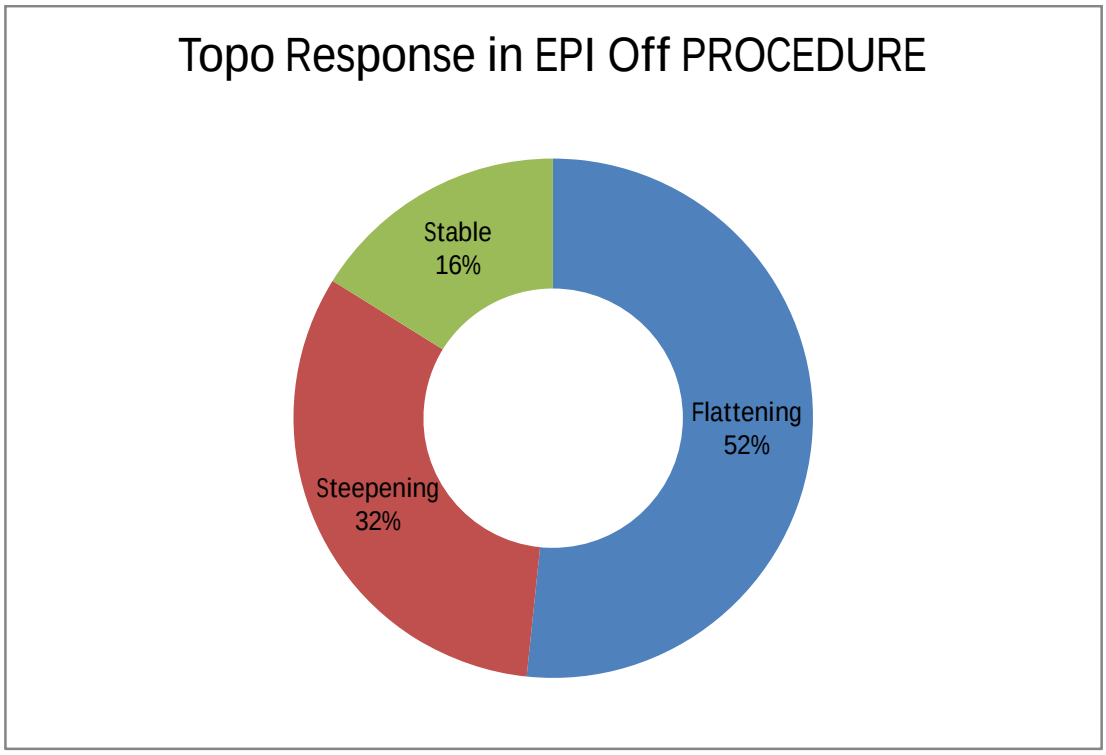


Table:9

VISION RESPONSE IN EPI ON PROCEDURE

S.no	Vision	Eyes=14
1	Improvement	8 (57.2%)
2	Stable	3 (21.4%)
3	Decrement	3 (21.4%)

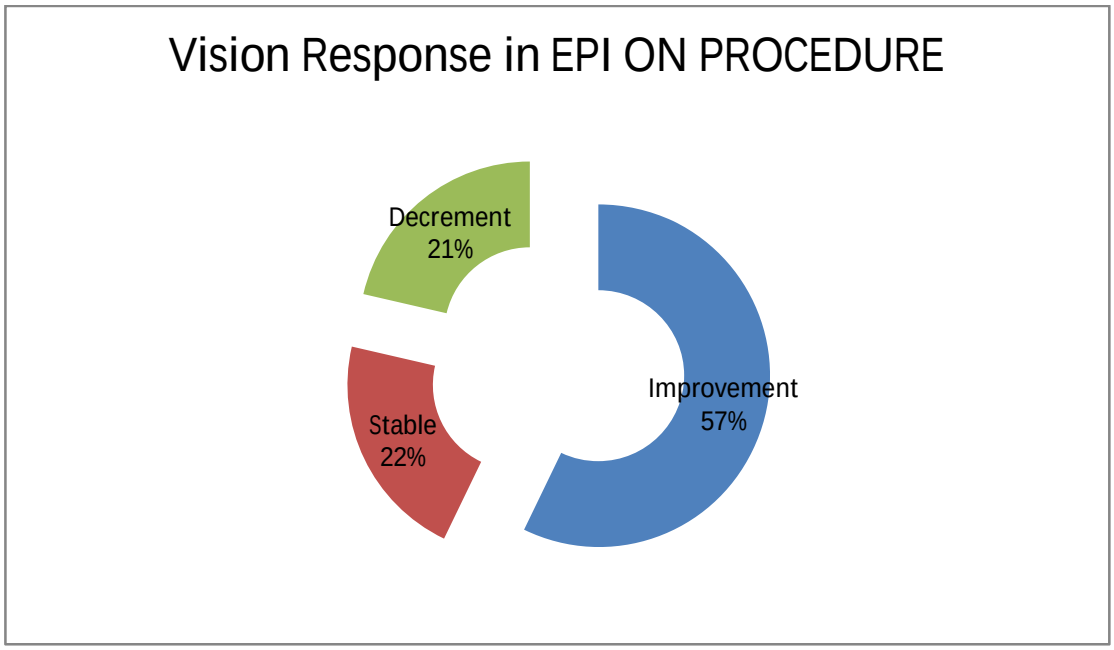


Table:10

VISION RESPONSE IN EPI OFF PROCEDURE

S.no	Vision	Eyes=31
1	Improvement	20
2	Stable	5
3	Decrement	6

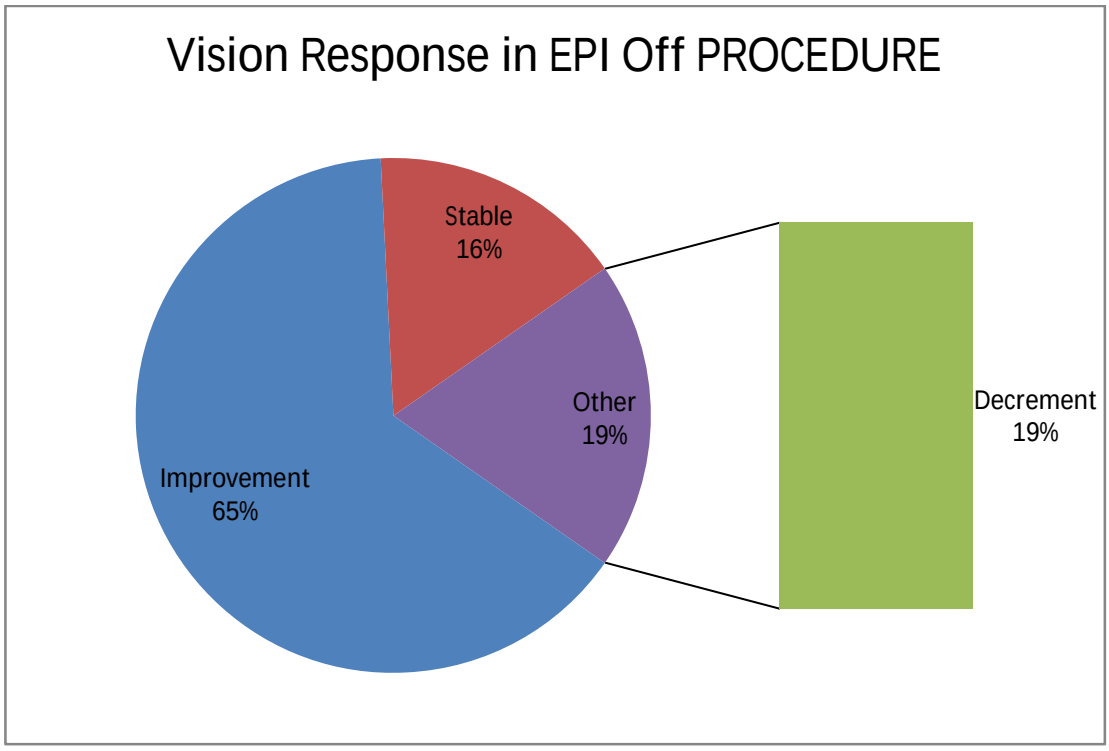


Table:11

OF THE VISION IMPROVEMENT CASES COMPARISON

Snellens	Vn improvement Epi on		Vn improvement Epi off		
	UCVA	BCVA	UCVA	BCVA	
1 line	1	-	3	7	Chisq = 1.92, p – 0.1
2 line	3	2	4	3	Chisq - 0.01 p - 0.9
3 line	2	-	3	-	
	Ucva : chisq – 0.37, p – 0.8		Bcva: chi –3.36 , p – 0.1		

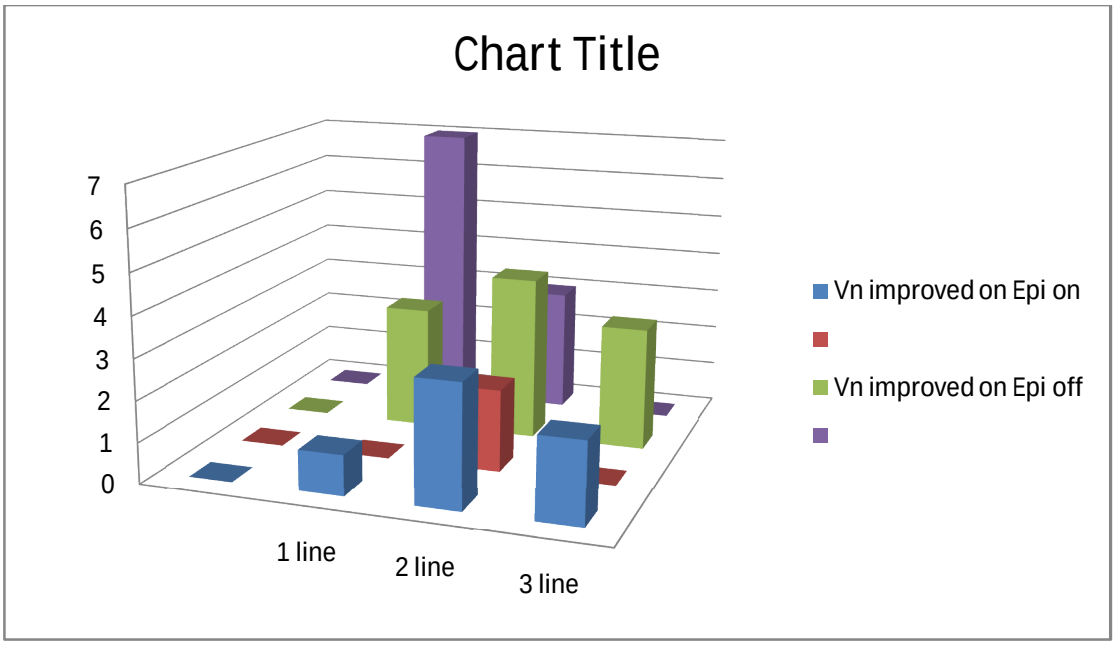


Table:12

VISION RESPONSE ON DEMONSTRABLE FLATTENING IN TOPOGRAPHY

S.no	On flattening	Epi on	Epi off
1	Vision betterment	5	11
2	Vision stable	2	5
3	Vision deterioration	0	0

Chi sq – 0.02, p – 0.8

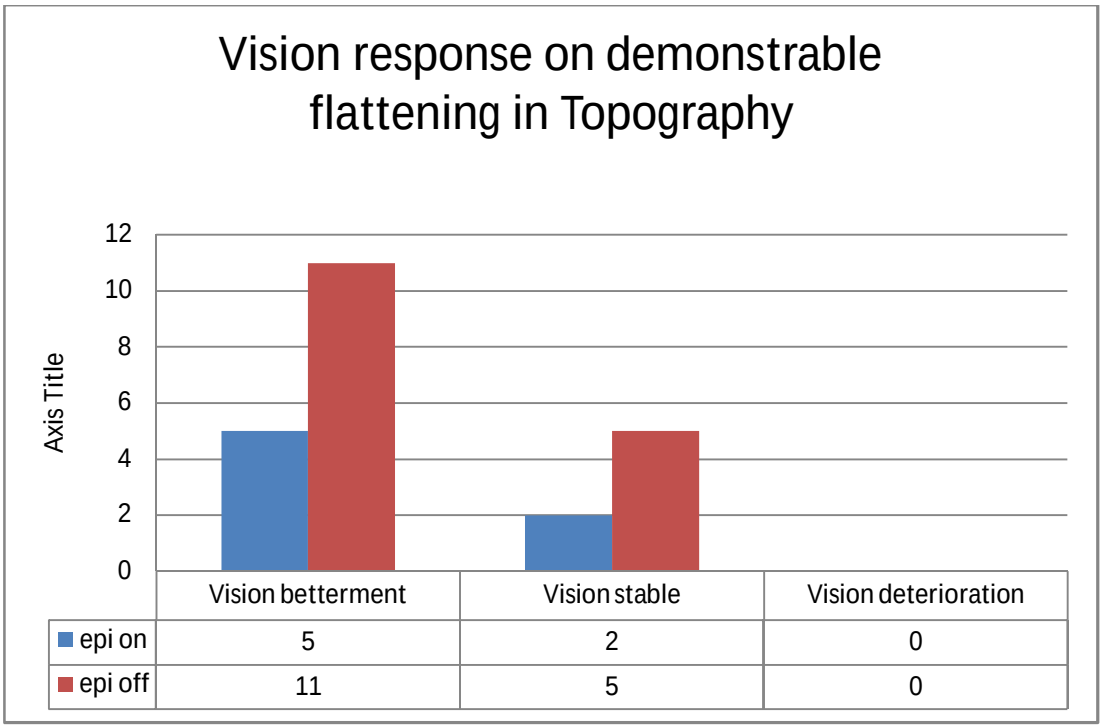


Table:13

Vision response on demonstrable Steepening in Topography

S.no	On steepening	Epi on	Epi off
1	Vision betterment	1	5
2	Vision stable	0	0
3	Vision deterioration	2	5

Chi sq – 0.26, p – 0.6

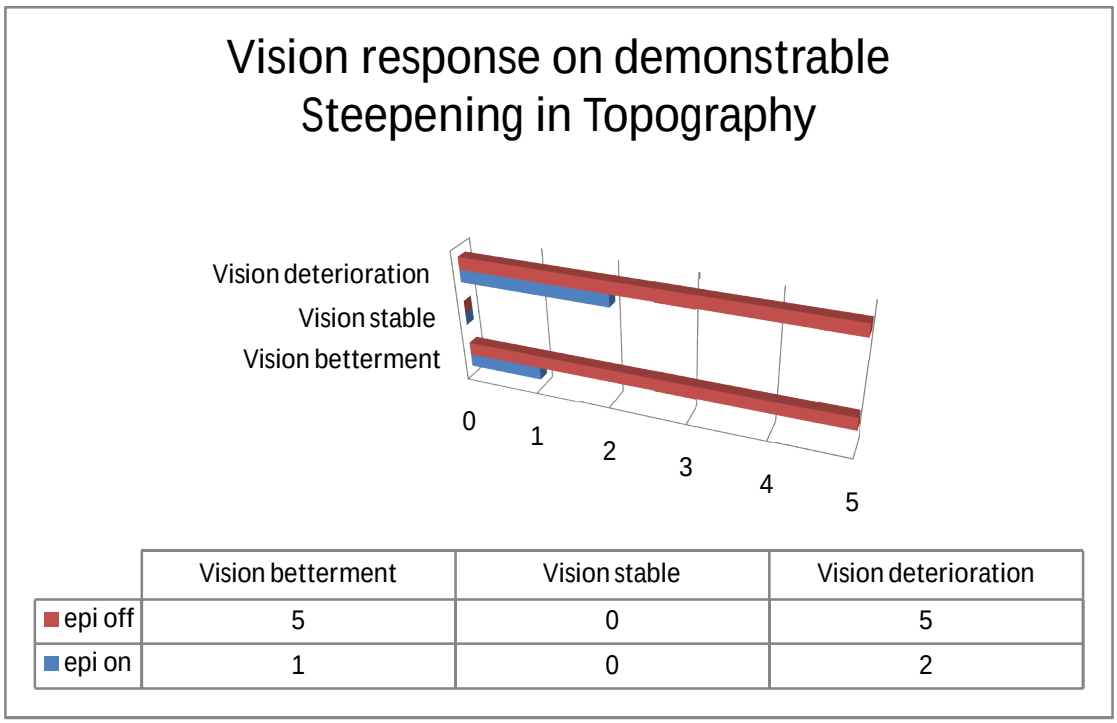


Table:14

Vision response on stable Topography

S.no	On stable topo	Epi on	Epi off
1	Vision betterment	1	5
2	Vision stable	0	0
3	Vision deterioration	2	5

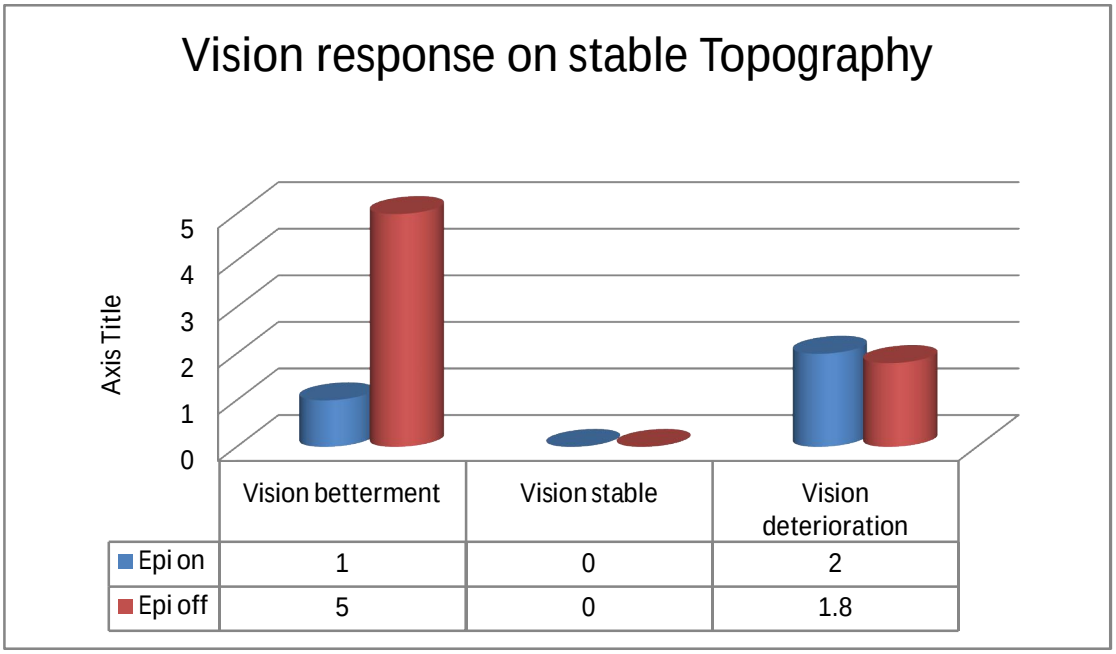
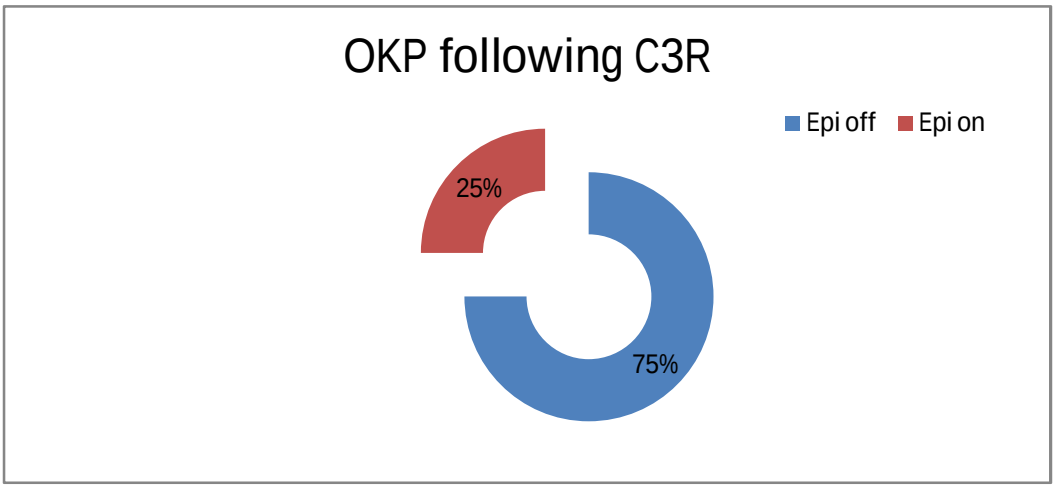


Table:15

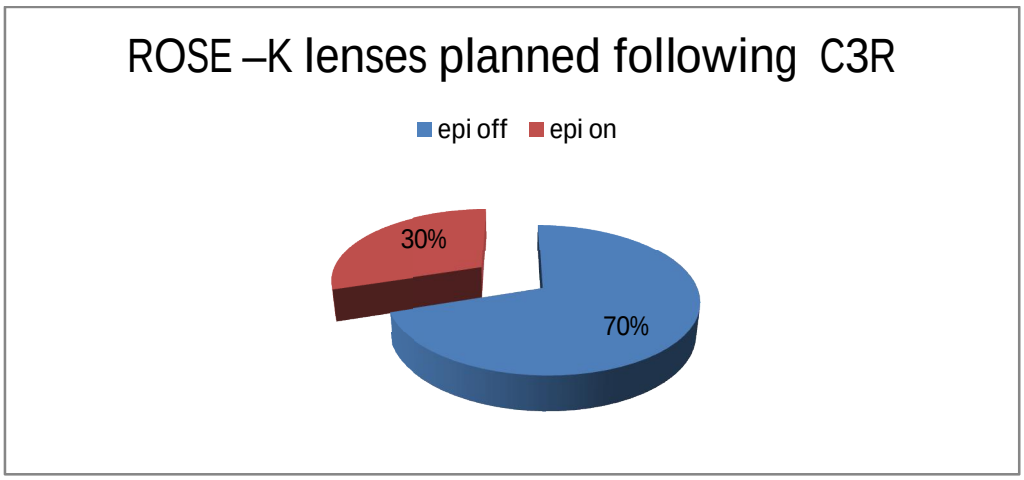
OKP FOLLOWING C3R

S no	C3R	OKP
1	Epi off	3
2	Epi on	1



ROSE –K lenses planned following C3R

S.no	C3R	Rose K lens
1	Epi off	7
2	Epi on	3



STATISTICAL ANALYSIS

Variables	EPI OFF		EPI ON		t value	P value	
	Mean ± SD	Range	Mean ± SD	Range			
Age	22.29 ± 6.42	12 to 35	20.36 ± 6.22	11 to 32	0.944	0.3	Not sig
cct	0.49 ± 0.03	0.45 - 0.55	0.43 ± 0.02	0.4 - 0.453	6.965	0.00	Sig
Pre K1	56.02 ± 4.31	49.4 - 63.4	56.51 ± 4.74	49.22 - 62.13	0.33	0.7	Not sig
Pre K1 Axis	92.48 ± 36.5	13 - 179	103.79 ± 36.13	35 - 153	0.96	0.3	Not sig
Pre K2	49.9 ± 3.66	42.7 - 57.6	51.18 ± 4.92	42 - 57.7	0.96	0.3	Not sig
Pre K2 Axis			95.29 ± 70.309	6 - 179			
Post K1	55.99 ± 4.76	48.6 - 65.5	56.58 ± 5.57	48.2 - 67.8	0.36	0.7	Not sig
Post K1 Axis			102.7 ± 31.93	40 - 156			
Post K2	49.93 ± 4.19	42.69 - 60.81	51.58 ± 5.1	44.8 - 59.72	1.13	0.2	Not sig
Post K2 Axis	87.58 ± 67.52	4 - 180	83.93 ± 66.9	6 - 179	0.168	0.8	Not sig

Paired t test		t	Sig. (2-tailed)
Epi off	pre_k1 - postk1	0.062	0.951
Epi off	prek2 - postk2	0.05	0.96
epi on	pre_k1 - postk1	0.117	0.909
epi on	prek1axis - postk1axis	0.336	0.742
epi on	prek2 - postk2	0.614	0.55
epi on	prek2axis - postk2axis	0.953	0.358

Not sig ➔ there is no significant diff b/w pre vs post.....

PEARSON CORRELATION B/W VARIABLES		EPI OFF		EPI ON	
Pre k1	pre k2	78.30%	**0.00**	88.70%	**0.00**
Pre k1	post k2	62.70%	**0.00**	85.50%	**0.00**
Pre k2	post k1	66.10%	**0.00**	82.40%	**0.00**
pre k2	post k2	74.60%	**0.00**	88.40%	**0.00**
pre k1	post k1	84.50%	**0.00**	91%	**0.00**
post k1	post k2	83.60%	**0.00**	90.7	**0.00**
pre k1 axis	pre k2 axis			-63%	**0.00**
pre k1 axis	post k1 axis			94.60%	**0.00**
pre k1 axis	post k2 axis			-56%	**0.00**
pre k2	pre k1			89%	**0.00**
pre k2 axis	pre k1 axis			-63%	**0.00**
pre k2 axis	post k1 axis			-58%	**0.00**
pre k2 axis	post k2 axis			79%	**0.00**
post k1 axis	pre k2 axis			-58%	**0.00**
post k1 axis	post k2 axis			-58.80%	**0.00**

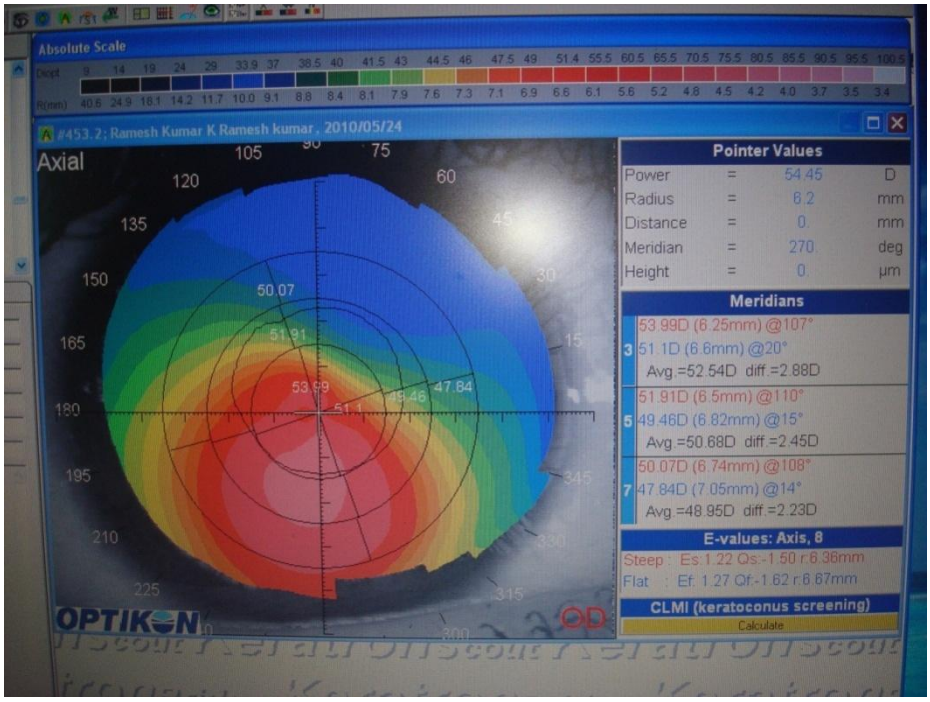
Positive correlation ➔ as var 1 increases var 2 increases

Negative correlation ➔ as var 1 increase var 2 decreases

The pairs given above are highly significant.

PATIENT PROFILE AT A GLANCE

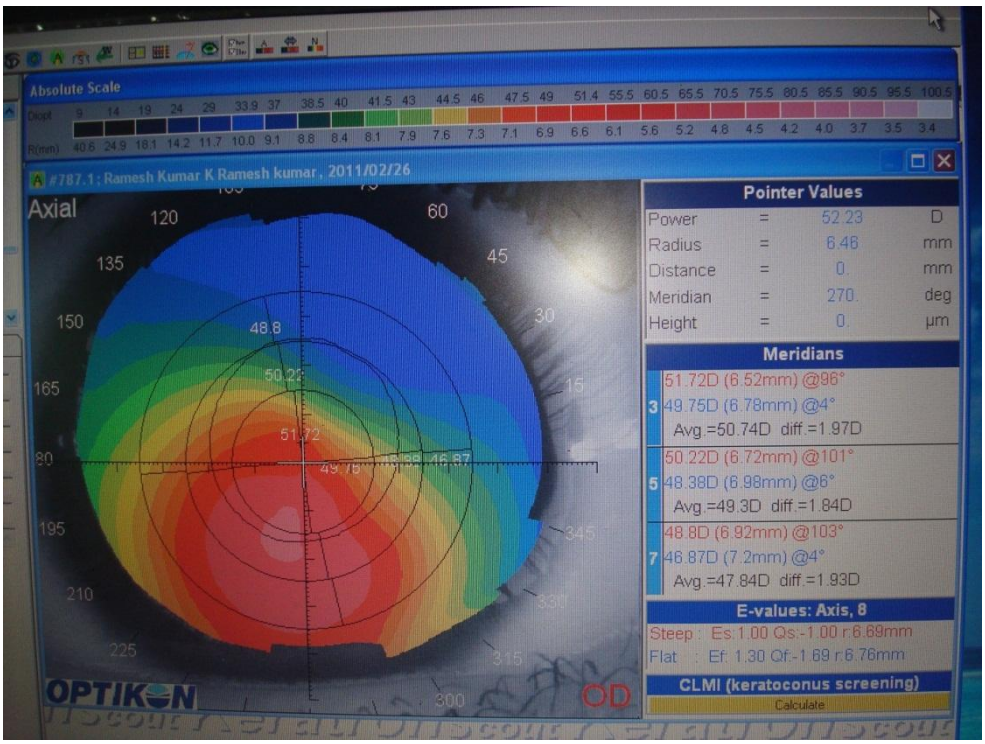
- 40 cases of Keratoconus
- 23 Males and17 Females
- Minimum Age- 11years
- Maximum Age- 35 years
- Least BCVA-2/60
- Highest BCVA-6/12
- Least Cylinder-1.0 D
- Highest cylinder- 12.0 D
- Steep K values between 49 and 63D

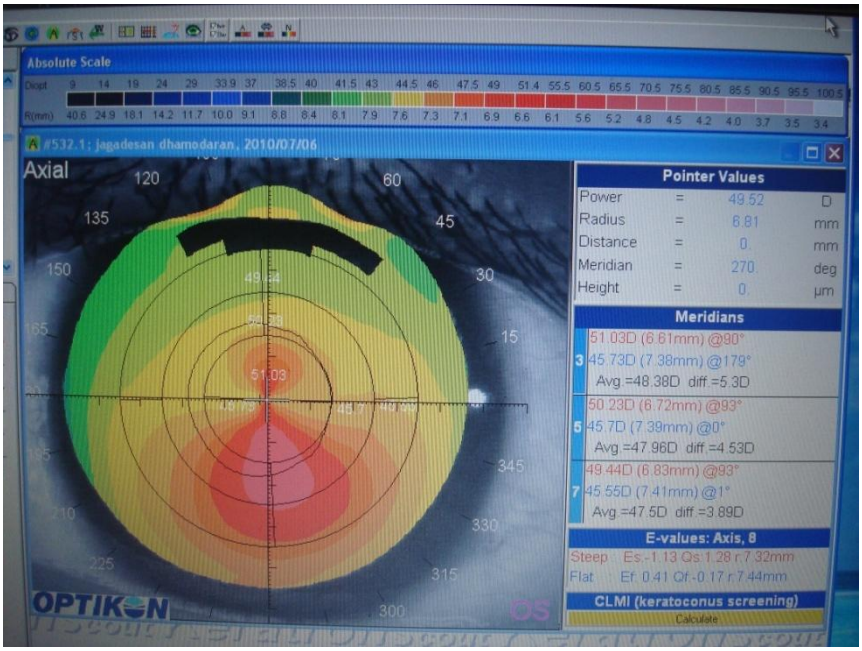


PRE C3R

RAMESH KUMAR 27/m demonstrating flattening in topo values following C3R

POSTC3R

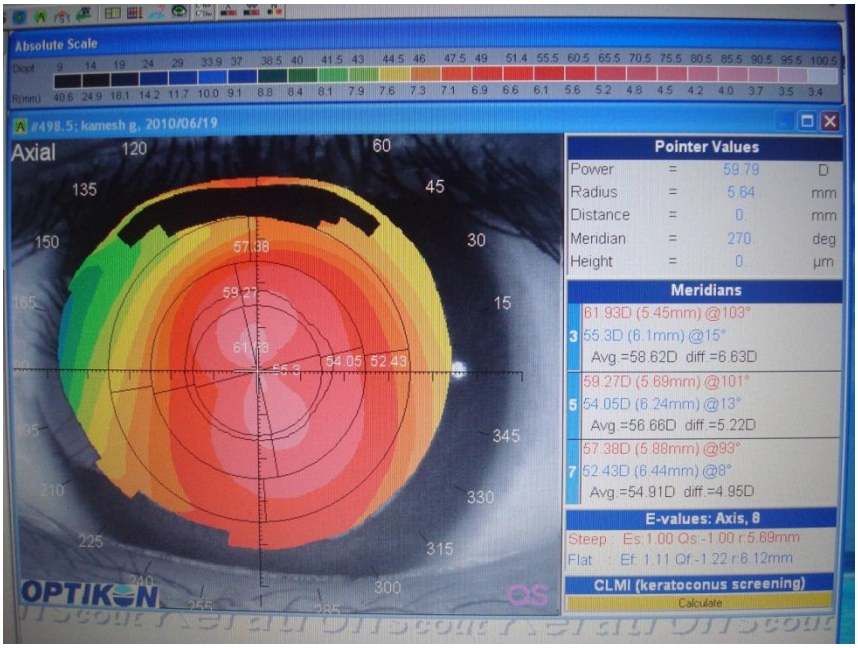




PRE C3R

JAGADEESAN 22/M demonstrating irregular bowtie pattern in topography

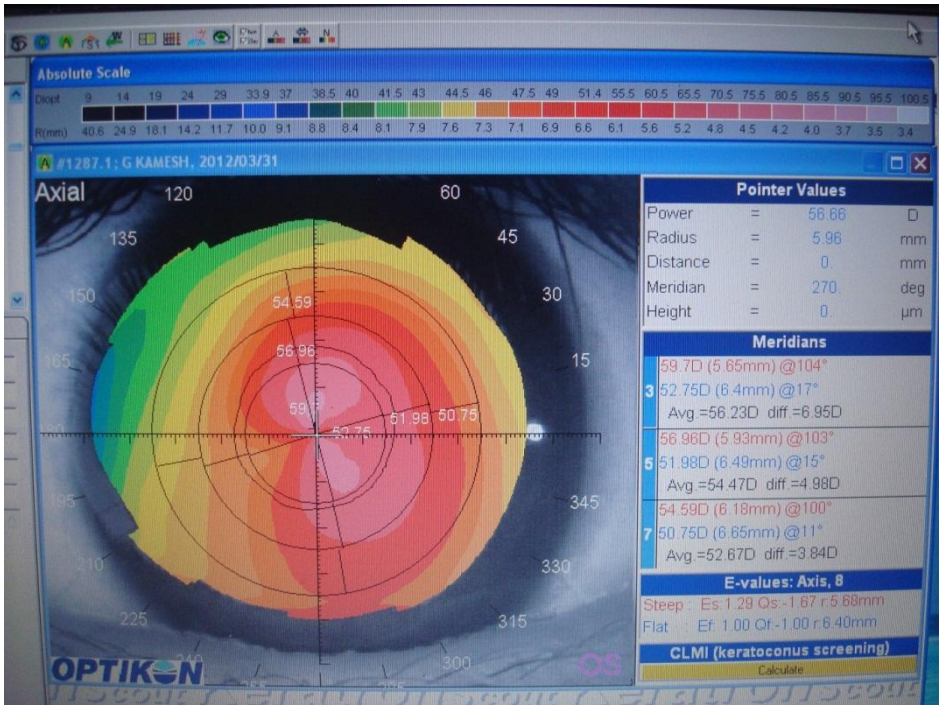
POST C3R

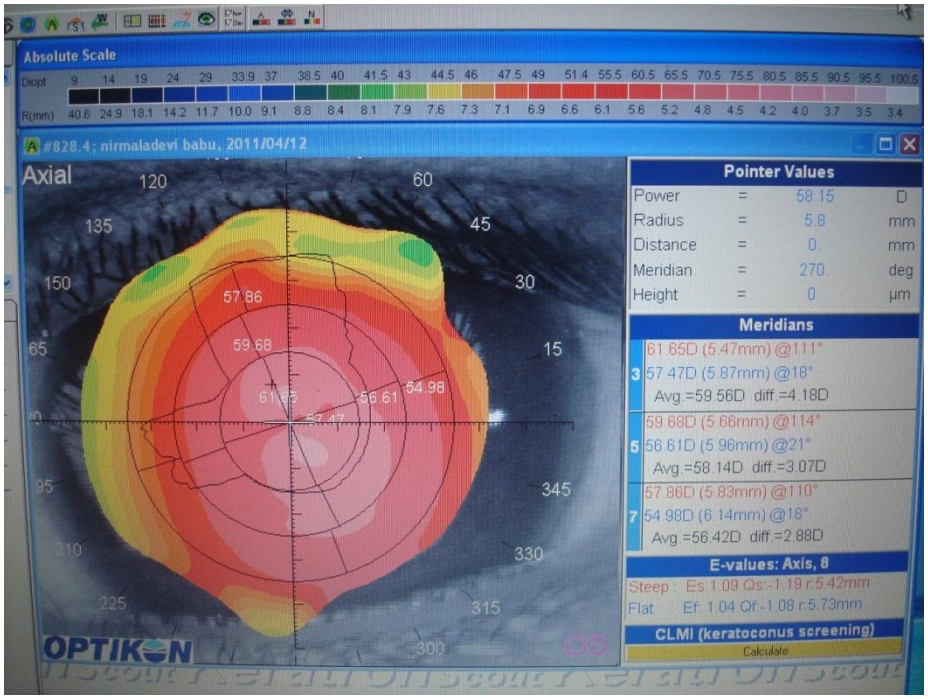


PRE C3R

KAMESH G 23/M symmetrical bowtie patternrespoding well to C3R with flattening

POST C3R

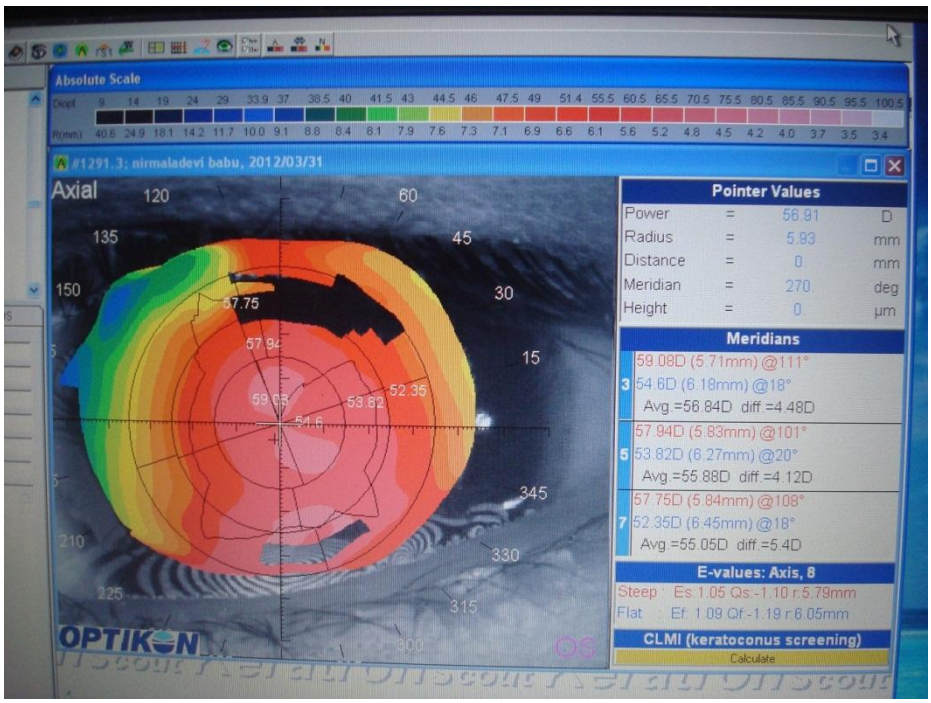


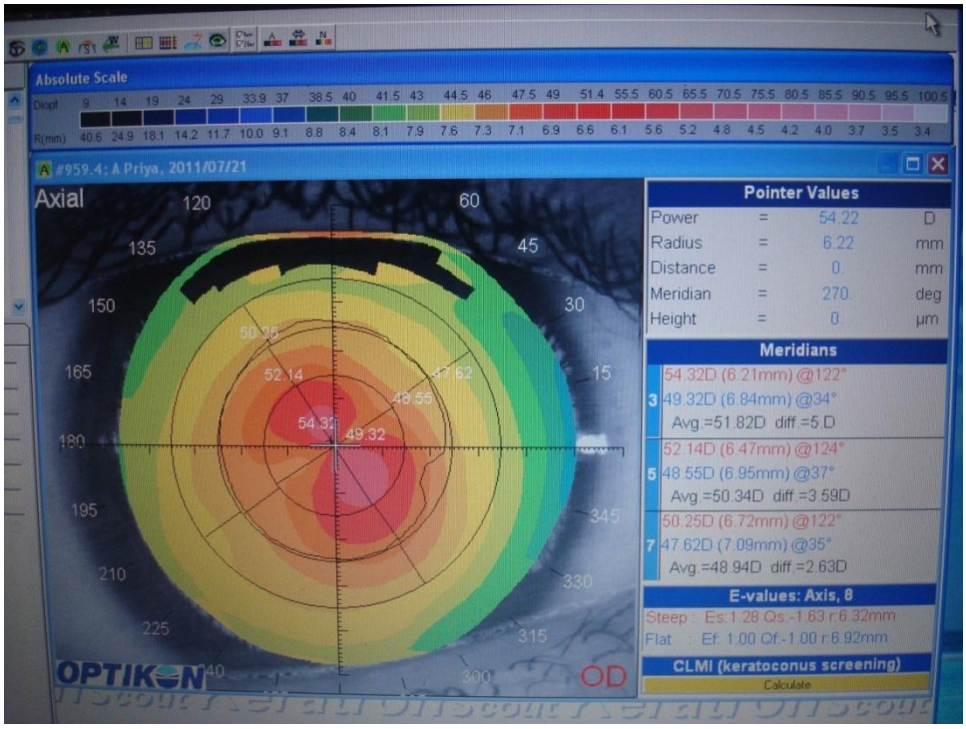


PRE C3R

NIRMALA DEVI 20/F flattening of topo values following Epi-on procedure in C3R

POST C3R

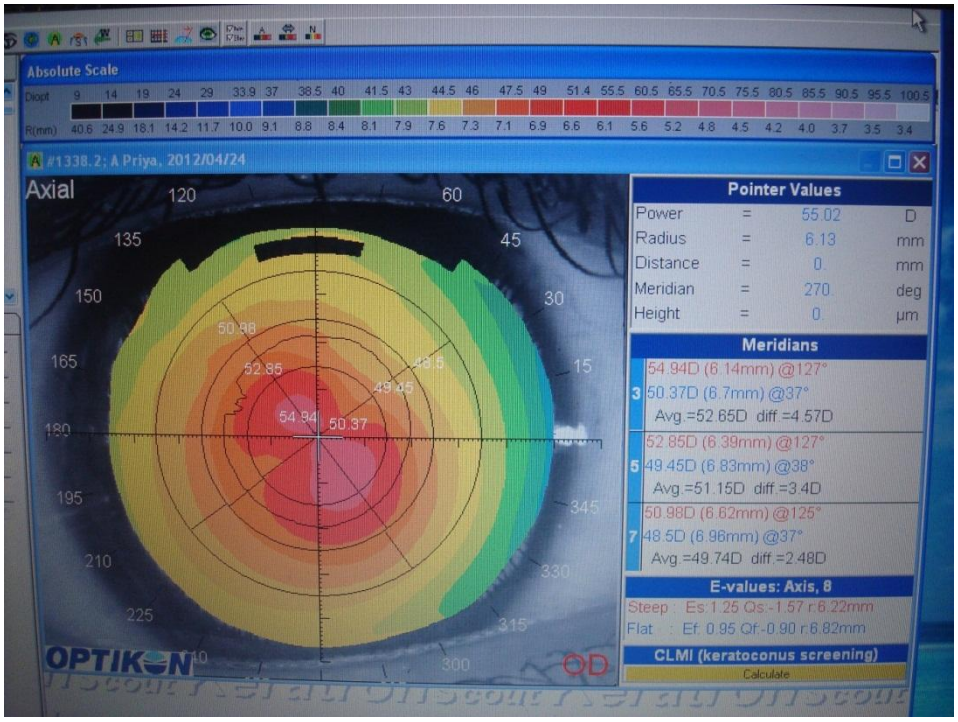


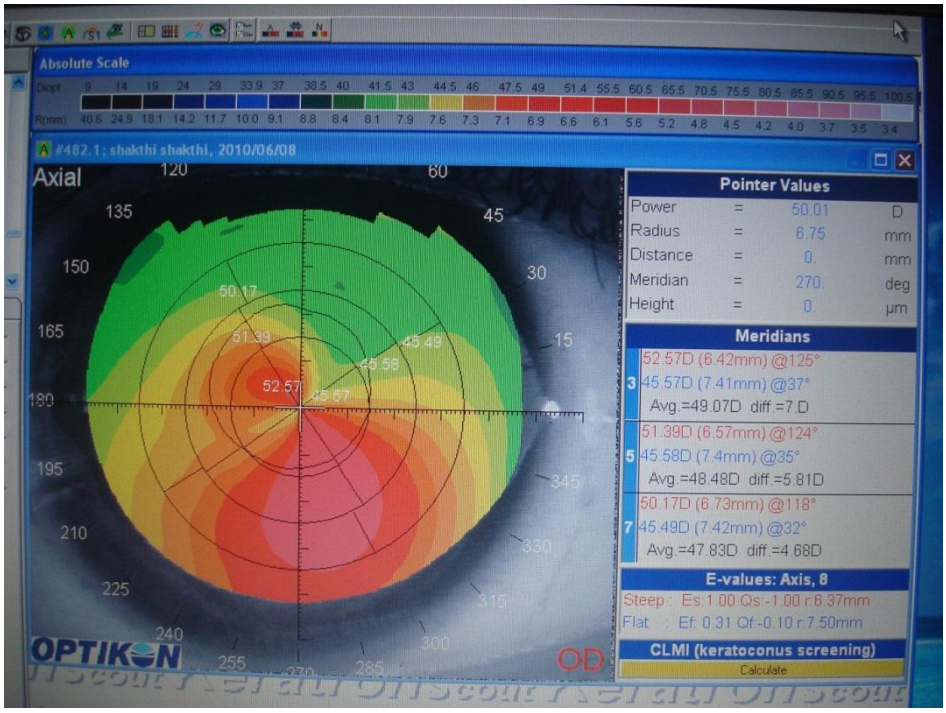


PRE C3R

A.PRIYA 26/F demonstrating stable topo following C3R

POST C3R

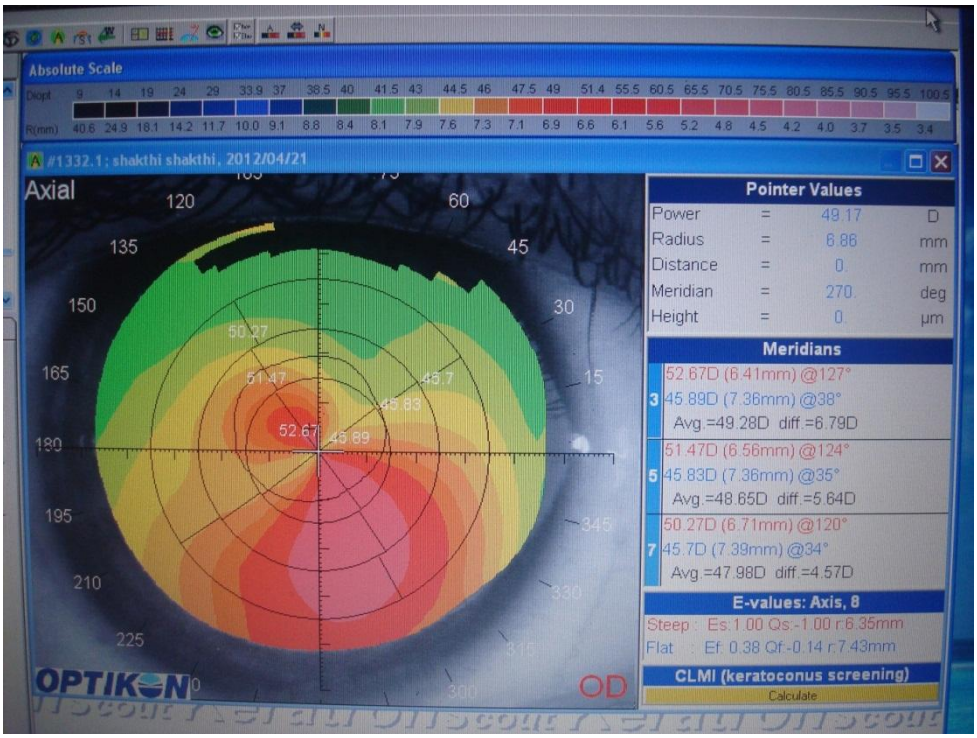


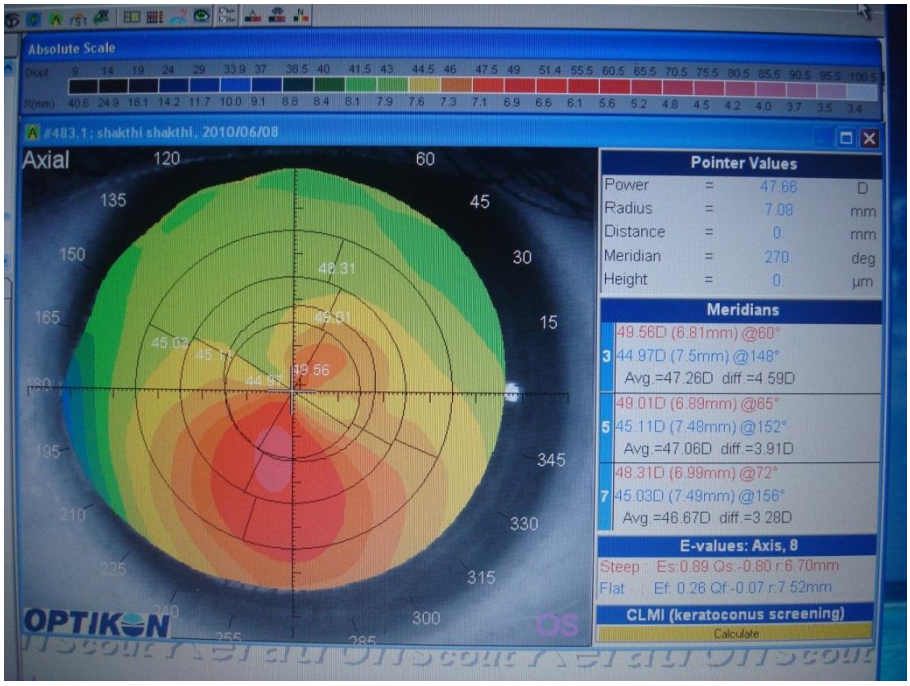


PRE C3R

SHAKTHI 27/F RE demonstrating irregular bowtie with skewed deviationwith stable topo

POST C3R

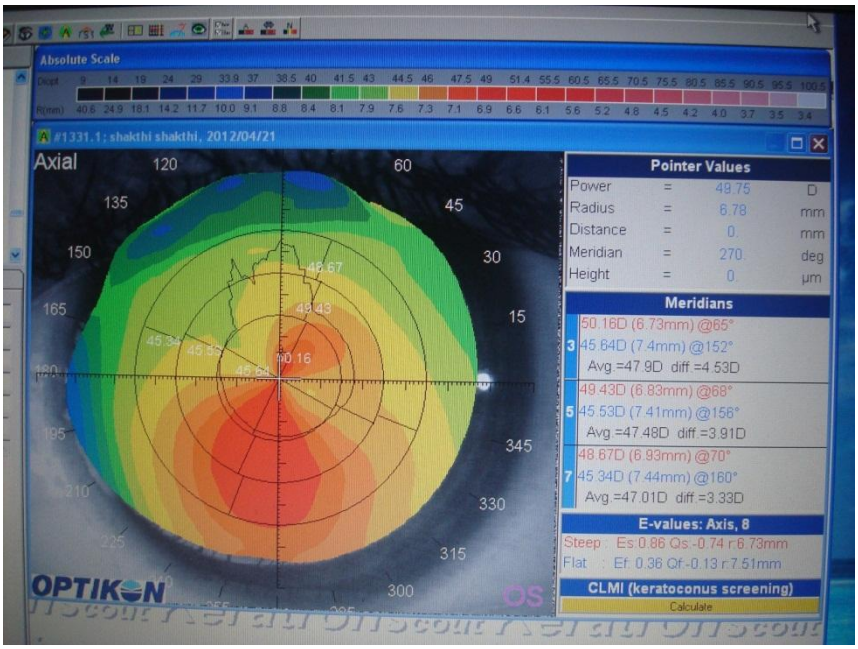




PRE C3R

SHAKTHI 27/F LE demonstrating irregular bowtie with skewed deviation with steepening on C3R

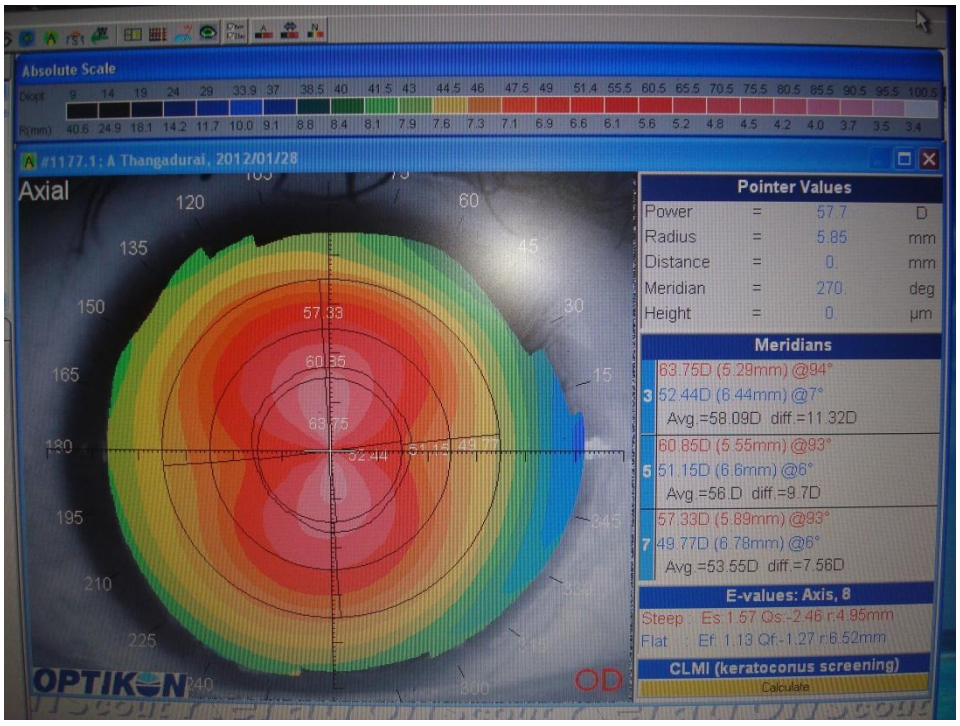
POST C3R



PRE C3R

THANGADURAI 32/M HIGHEST TOPO VALUE OF 63 IN OUR SERIES

POST C3R



OBSERVATION

45 eyes of 40 patients underwent Corneal Collagen Crosslinking procedures.

1. Patients with corneal thickness 400-450 microns underwent Epi – on C3R procedure and more than 450 microns by Epi-off C3R procedure. In our series Epi -on C3R was done on 14 eyes and Epi-off procedure on 31 eyes.
2. Analysing the age distribution we had a range of 11-35 yrs and the maximum sample in the age group 10-15 yrs and 21-35yrs. Case identification is high in 10-15yrs children seeking refraction for defective vision and similarly case identification is high in 21-25 yrs age group as patient need for refractive procedures is high in this age group.
3. In our case series, sex distribution was almost equally poised in both gender.
4. In laterality, only 5 patients underwent both eyes C3R procedures, 4 were Epi-off and 1 Epi-on C3-R.

5. Interestingly on analysis of the K reading of our series the maximum k value was 63.4D and minimum K was 49.4 D .As a revelation, steeper corneas were not necessarily extremely thin and were also subjected to Epi-off C3-R procedures.

6. Pachymetry values were the clear indicators of Epi-on or Epi-off procedures. The minimum pachy value was 405 and maximum 552microns. The maximum distribution was seen between 450-520 microns.(56%).

7. On analysing the post procedure Epi-on response in topography, 11 eyes out of 14 showed good therapeutic response. Flattening was seen in 50% and stability in 29%. 3 cases showed steepening in K values. Out of which 2 patients were in the age group 10 -15 yrs showing the progressive nature of the disease .

8. On topographic response in Epi-off procedure, flattening seen in 52% and stability in 16% of the eyes. Few patients showed progression in spite of C3R. These include

    - Three patients with initial K reading of more than 58 D
    - Five patients with central corneal thickness less than 480 microns

The flattening response after Epi-on and Epi-off was almost equal.

9. The visual improvement following Epi on C3R was 57%. Stable vision noticed in 21.4% and visual decrement in 21.4%. The decrement is noticed in one patient with initial k reading of more than 60D and one patient with high cylinder values.The visual response in Epi-off C3R showed improvement in 65% and stability in 16%. The visual decrement was seen in 19%. The visual decrement is analysed to be in

    - Patients with initial K reading of more than 60D
    - Patients with low BCVA at presentation
    - Patients with high initial cylinder values

10. In our case series there was visual improvement of one line in 11 eyes., 2 lines in 12 eyes, and 3 line improvement in 5 eyes. The maximum of three line improvement is seen in 2 eyes following Epi –on C3R and 3 eyes following Epi-off procedures.

11. The visual improvement was not only seen on topographic flattening but also in patients with topo steepening, and this might be due to the stability induced by increase in corneal rigidity following the procedure.

12. 4 patients in our series had uncontrolled progression and finally were taken up for optical keratoplasty.

DISCUSSION

Our study reports on a cohort from the south Indian population, like most of the other studies of its kind. Our study aims at establishing that corneal collagen crosslinking procedure with riboflavin is very effective in arresting the progression of keratoconus.

The success of this procedure is not surprising because lot of invitro studies and animal models have proved beyond doubt that there is significant increase in corneal rigidity post procedure, on corneas which were proved to have reduced tensile strength measured biomechanically.

The best of our results were with 3 line improvement as seen in 5 patients of which 2 patients had undergone Epi- on and 3 patients Epi-off C3-R procedures.

We never had a chance of dealing with severe post procedure complications. However in few patients we noticed stromal haze and delayed epithelialization especially in Epi –off C3-R procedures which all recovered well with regular medications. Few patients were contact lens wearers and were allowed to restart the contact lens schedule after four weeks. Co prescription of preservative free tear substitute significantly increased their comfort levels.

We also set on to compare closely the results of C3-R either Epi-on or Epi-off procedure on keratoconus patients. We analysed the comparative changes on topographic values, pachymetry and visual outcomes. We did not appreciate a very statistically significant difference in our results of either procedure. Literally search of other similar studies also did not find much difference between the outcomes of Epi on and Epi off C3R.

In a developing country and in a tertiary Government Eye Hospital like us where most of our patients received free treatment or subsidised by insurance, this is a big boon considering its low establishing cost and simplified outpatient procedure status. Technically also the ease of the procedure with good standard operating protocols, provides a easy learning curve for all of us to perform.

Corneal Collagen Crosslinking procedure has excellent efficacy in controlling and mitigating the disease progression as evidenced by our study.

CONCLUSION

- C3R is the only promising treatment available till date to stop the progression of keratoconus.

- Statistically no difference in visual improvement was noted between Epi on and Epi off C3R procedures.

- Patients who present with more than 60D pre K values, poor vision of less than 3/60 and pachymetry values less than 400 microns may be directly considered for keratoplasty.

- **C3R is the standard treatment to arrest the progression and permanently strengthen the inherently weakened corneas.**

PART III

PROFORMA – KERATOCONUS C3R

Name Age / Sex CC No

OP No

H/OPresenting Complaints

H/O Present illness

Past history

H/O Previous Ocular Surgery

H/O Wearing Spectacles

H/O Contact lens use

Family H/O

Personal H/O

O/E

General examination

Head posture

CVS

RS

Slit lamp examination

Conjunctiva RE LE

Cornea

Extra ocular movements

Anterior chamber

Iris

Pupil

Lens

Fundus

UCVA

BCVA

AR / subjective

Keratometry value

C Topography

Sim K1

Sim K2

Difference

C Pachymetry

Consent:

I …….. aged……..S/O D/O W/O…….....

was clearly explained about the disease condition and the proposed treatment procedure and fully consent for the same

Sign of patient Sign of relative

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KEY TO MASTER CHART

CCno.	-	Cornea OP no
CCT	-	Central corneal thickness
SIM K1	-	Steep keratometry values
SIM K2	-	Flat keratometry values
Vn	-	Vision
UCVA	-	Uncorrected visual acuity
BCVA	-	Best corrected visual acuity
Cyl	-	Cylinder values

EPI OFF C3R

S. No	Name	CC No	Age	Sex	Age	CCT	Topo (pre)					Post (Topo)					Vision		Vision	
							K1	Axis	K2	Axis	CYL	K1	Axis	K2	Axis	CYL	UC VA	BC VA	UCV A	BC VA
1.	Kamesh	915	23	M	LE	0.488	61.93D	103	55.3D	103	6.63	59.7D	104	52.75	17	6.95	6/60	6/12	6/60	6/12
2.	Jagadesan	1998	22	M	LE	0.509	51.030	90	45.73D	179	5.3	51.140	97	43.87	7	7.27	6/18	6/9	6/12	6/6
3.	Muthuraman RE	1541	12	M	RE	0.533	58.46	86	51.71	176	6.75	59.95	87	50.75	177	9.2	6/60	6/24	6/36	6/24
4.	Muthuraman LE				LE	0.535	55.3	86	50.83	176	4.47	55.8	82	49.77	172	6.03	6/18	6/12	6/12P	6/9
5.	Senthil	1303	24	M	RE	0.461	53.5D	98	43.7	8	9.8	58.79	75	52.7	165	6.09	6/36	6/6	6/60	6/12
6.	Shanmitha florence	3454	35	M	LE	0.479	56.88	35	51.71	125	5.17	58.29	34	53.52	124	4.77	6/60	6/18	6/18	6/9
7.	Rajesh	1468	15	M	RE	0.510	49.4D	139	47.86	49	1.54	48.58	125	46D	45	2.58	6/2	6/6	6/12	6/6
8.	Selvam	1747	23	F	LE	0.450	59.08	87	50.54	177	8.54	58.05	90	50.32	67	7.73	3/60	6/60	4/60	6/36
9.	Aysha Hazeena	3657	20	M	LE	0.475	51.94	52	44.6	142	7.34	52.59	53	44.48	143	8.11	6/60	6/18	6/60	6/9
10.	Kamash Kannan	5471	23	M	LE	0.510	58.67	98	53.4	8	5.27	57.04	103	51.68	13	5.36	6/60	6/24	6/60	6/18
11.	Chandhini	1522	13	M	LE	0.468	60.24	77	51.94	167	8.33	58.8	83	51.25	173	7.55	6/24	Nip	6/24	6/12
12.	Koperundevi	7872	20	F	RE	0.451	59.12	89	53.13	8	5.99	58.55	98	50.9	8	7.65	6/60	6/36	6/24	6/18
13.	Ramesh kumar	1654	27	M	RE	0.454	53.99	107	51.10	21	2.89	51.720	96	49.75	4	1.97	6/60	6/18	6/60	6/24
14.	Kavi Priyan	5743	13	M	RE	0.452	63.03	125	57.65	38	5.38	65.49	128	58.4	38	7.09	2/60	6/36	2/60	6/60

15.	Sakthi RE	413	27	F	RE	0.519	52.51D	125	45.57D	37	6.94	52.67	127	45.89	38	6.78	3/60	6/36	6/60	6/18
16.	Sakthi LE				LE	0.520	49.5	60	44.97	148	4.53	50.16D	65	45.64	152	4.52	4/60	6/36	6/36	6/9
17.	Senthil K RE	1587	23	M	RE	0.455	54.12	101	49.73	11	4.39	48.84	105	44.41	15	4.43	5/60	6/36	6/60	6/12
18.	Senthil K LE				LE	0.477	49.42	79	A4.75	169	4.67	48.84	83	44.69	173	4.15	6/18	6/9	6/18	6/9
19.	Vasudevan	531	23	M	LE	0.468	52.36	13	51.57	103	0.79	61.67	172	60.81	82	0.86	6/60	6/18	4/60	NIP
20.	Nandhini RE	1513	26	F	RE	0.545	52.51	135	45.99	45	6.52	51.63	139	44.16	49	7.47	2/60	6/18	4/60	6/18
21.	Nandhini LE				LE	0.552	61.24	45	50.25	135	10.99	60.9	51	52.49	134	8.41	2/60	6/60	3/60	6/60
22.	Sindhu	8610	27	F	LE	0.505	51.16	112	48.4	20	2.76	49.12	101	48.07	10	1.05	6/36	6/12	6/36	6/12
23.	Mohammed	6294	34	M	RE	0.510	58.29	34	53.52	124	4.77	56.88	35	51.57	125	5.31	6/60	6/36	6/60	6/18
24.	Preethi	1395	15	F	RE	0.488	56.02	105	52.01	15	4.01	56.07	104	52.04	15	4.03	4/60	NIP	5/60	6/60
25.	Sunil	3534	25	M	LE	0.525	56.99	62	51.87	152	5.12	56.7	59	50.4	149	6.3	6/60	6/36	6/60	6/36
26.	Abdul Riaz	2990	16	M	RE	0.464	61.68	86	49.49	176	12.19	62.84	90	50.57	176	12.27	2/60	6/60	2/60	4/60
27.	Santhosh	7539	13	M	LE	0.453	60.3	79	51.9	169	8.13	56.28	56	52.08	149	4.2	4/60	6/18	6/36	6/18
28.	Priya anadhi	6628	26	F	RE	0.475	54.32	122	49.32	34	5.0	54.94	127	50.37	37	4.57	6/24	6/12	6/60	6/12
29.	Thangadurai	8488	32	M	RE	0.457	63.4	96	52.04	6	11.36	63.75	96	52.44	6	11.31	6/36	6/18	6/36	NIP
30.	Geetha	4664	17	F	LE	0.520	51.04	179	42.69	3	8.35	50.76	160	42.69	180	8.07	6/36	NIP	6/36	6/18
31	Amutha	1576	29	F	LE	0.509	59.26	162	53.90	72	5.36	59.26	162	53.5	72	5.76	2/60	NIP	3/60	NIP

EPI On C3R

S.No	Name	CC No	Age	Sex	AGE	CCT	Topo (pre)					Post (Topo)					Vision		Vision	
							K1	Axis	K2	Axis	Cyl	K1	Axis	K2	Axis	Cyl	UCVA	BCVA	UCVA	BCVA
1.	Anandakumari	1523	13	F	LE	0.444	62.06	84	57.72	174	4.34	67.83	77	59.72	167	8.11	3/60	6/18	2/60	Nip
2.	Joel Kingston	6778	11	M	LE	0.421	49.4	139	47.86	49	1.54	48.64	120	46.78	45	1.86	6/24	6/12	6/12	6/9
3.	Senthil	1587	24	M	LE	0.446	49.22	83	44.99	173	4.23	48.2	100	44.9	10	3.3	6/12	6/9	6/18	6/9
4.	Nirmala devi	5399	20	F	LE	0.405	61.65	111	57.47	18	4.18	59.08	111	54.6	18	4.48	3/60	6/24	5/60	6/24
5.	Koperundevi	7872	20	F	LE	0.431	58.56	89	51.61	179	6.95	58.56	89	57.6	179	0.96	6/60	NIP	6/60	NIP
6.	.Jagadeswari	1467	18	F	LE	0.401	62.13	90	54.67	6	7.46	61.33	84	54.07	6	7.26	6/60	6/36	6/24	6/12
7.	Sanjay	8475	13	M	LE	0.406	59.08	86	50.54	177	8.54	58.05	94	50.32	169	7.73	5/60	6/60	6/36	NIP
8.	Lakshmi priya	2904	26	F	RE	0.453	55.3	35	50.83	176	4.47	55.8	40	49.7	172	6.1	6/36	NIP	5/60	NIP
9.	Lakshmi priya				LE	0.440	58.65	153	55.13	62	3.52	56.32	132	53.28	60	3.04	5/60	NIP	6/12	NIP
10.	Yasmin parveen	4215	21	F	RE	0.423	50.11	145	42.02	58	8.09	50.16	136	44.8	46	5.36	6/36	6/12	6/60	6/9
11.	santhosh	7539	13	M	RE	0.437	58.09	100	51.66	10	6.34	62.02	104	55.54	37	6.48	3/60	6/18	6/60	6/18
12.	Surendran	1880	32	M	RE	0.420	60.12	137	57.45	55	2.67	60.02	156	57.36	58	2.66	4/60	6/60	5/60	6/60
13.	Pavithra	1136	22	F	LE	0.441	51.45	55	47.91	145	3.54	52.91	60	47.87	150	5.04	6/60	6/24	5/60	NIP
14.	Elumalai	9175	26	m	RE	0.434	55.26	146	46.68	52	8.38	53.18	135	45.56	58	7.62	6/60	NIP	6/60	NIP

LIST OF SURGERIES PERFORMED

S. No	Op.No	Name	Age	Sex	Dignosis	Surgery Performance
1	66064	Manikandan	26	M	LE UL chalazion	LEChalazion I & C
2	423464	Sivagami	40	F	LE nasal pterygium	LE Pterygium excision
3	46899	Vedhagiri	30	M	RE nasal pterygium	RE Pterygium excision AMG graft
4	9408	Yasmin	21	F	RE Keratoconus	RE EPI on C3R
5	46877	Anandakumar	18	M	Re sebaceous cyst	RE Sebaceous cyst excision
6	49182	Chellamal	50	F	LE nasal pterygium	LE Pterygium excision with auto graft
7	475426	Parasuraman	70	M	RE moorens	RE Peritomy © AMG
8	458529	Rajammal	70	F	RE acute dacryocystitis	RE DCT
9	3454	Shanmitha florence	36	F	RE keratoconus	RE EPI off C3R
10	24687	Savitha	50	F	LE corneal tear	Corneal tear suturing
11	466664	Ranjitham	70	F	LE dacryocystitis	LE External DCR
12	453628	Venkataiya	70	M	LE mature cataract	LE ECC PCIO
13	458571	Ponnammal	55	F	RE Mature cataract	RE ECCE © PCIOL
14	32416	Parasuraman	47	M	LE	LE Evisceration

					panophthalmitis	
15	467482	Ramamorthy	60	M	LE Immature cataract	LESICS © PCIOL
16	469930	Munusamy	80	M	RE nuclear sclerosis	RESICS © PCIOL
17	471150	Parvathy	55	F	RE fungal corneal ulcer	RE Therapeutic keratoplasty
18	472468	Kannan	19	M	LE fungal corneal ulcer	LE Therapeutic keratoplasty
19	472802	Annammal	60y	F	LE Immature cataract	LE SICS© PCIOL
20	33047	saroja	54	F	BE pscc	RE SICS@ PCIOL
21	64111	vedagiri	64	F	LE IMC	LE PHACO@ PCIOL
22	472238	poongavanam	60	F	BE IMC	RE SICS @ PCIOL
23	472802	Annammal	60	F	LE IMC	LE SICS @PCIOL
24.	412705	Rajadurai	55	M	RE IMC	RE SICS @PCIOL
25	475322	Manickam	76	M	LE perforated ulcer	LE Therapeutic keratoplasty
26	476544	Rajesh	24	M	RE bacterial ulcer	RE Therapeutic keratoplasty
27	479179	Chellam	56	F	BE IMC	LE PHACO @ PCIOL
28	9901	Selva celin	25	F	LE keratoconus	LE Epi on C3R
29	10546	Mohana krishnan	45	M	RE RD	RE RD surgery assisted
30	467720	Sivaraman	60	M	LE dislocated iol	LE PPV @IOL removal assisted
31	38264	Bala	45	M	Re lower lid tear	RE lid tear suturing
32	15678	Saranya	9	F	Infantile esotropia	Bimedial recession assisted

33	480103	Chitra	22	F	RE Keratoconus	RE Epi off C3R
34	22568	Raji	7	F	RE retinoblastoma	RE enucleation assisted
35	459221	Chandru	62	F	BE IMC	RE SICS @PCIOL
36	1997	Lakshmikandan	23	M	RE hydrops	RE LKP assisted
37	2978	sivaraj	56	M	RE PBK	RE OKP assisted
38	3569	mohammed	60	M	LE aponeurotic ptosis	LE ptosis surgery assisted
39	477999	nathan	64	m	BE grade III NS	RE SICS @ PCIOL
40	478502	Arumugam	60	M	LE IMC	LE PHACO@PCIOL